

DAWN Novel Oral Anticoagulants (NonVKA) Monitoring

User and Safety Manual

Rivaroxaban (Xarelto) Module

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Part

1 Novel Oral Anticoagulants Module User Manual



The Novel Oral Anticoagulants User Manual provides the steps and workflows needed to add, edit and manage patients on novel oral anticoagulants (eg Rivaroxaban) within the DAWN system safely and effectively.

DAWN is registered trademark of **4S Information Systems Ltd.** and represents a new era in software where the adaptability built into the software empowers the customers, with minimum IT professional help, to quickly get the information they require from their system without long delays.

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Part III

2 How To Use the Manual



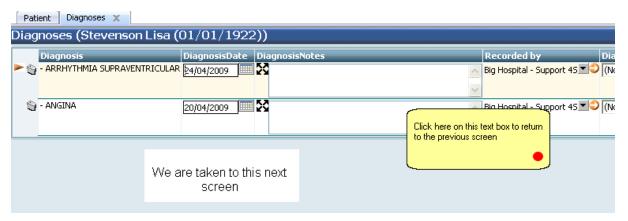
HOW TO USE THE MANUAL

If a text bubble asks you to 'Click Here' and a red circle is present on the bubble, you will be able to click on the link to take you to the next screen.

For example, clicking on the link on the image below will take you to another screen below:



2.1 Hyperlinks move to the Next Screen



Hyperlinks help you to move through the electronic manual easily.

Part IIII

3 Safety Manual

Introduction

This document is intended to highlight potential safety issues that must be understood and addressed before using the DAWN Rivaroxaban module.

It is vital for the on-going safe operation of your software that users of the software are aware of the Safety Instructions as detailed in this manual. Please keep this manual in a safe place for ready referral by your staff.

What Key Safety Areas Have Been Identified?

The following key safety areas have been identified:

Correct Patient Identification:

It is critical that the users ensure that they have identified the correct patient before taking action such as editing information, dosing, reports or taking any clinical action.

Avoiding Transcription or Transposition Errors:

Careful procedures should be derived and instituted to check that any transcription error or transposition of data cannot occur. The aim should be to eliminate completely any such potential for this type of error.

Checking Clarity of Dose Instruction to Patient / Healthcare Professional:

It is essential to ensure that any dose instruction messages printed / emailed / faxed are clear and unambiguous. As well as the format of the instruction itself, users need to check that the are clear so there is no scope for confusion.

Losing Track of a Patient:

It is vital that a patient does not get 'lost' within the system, e.g. treatment plan wrongly closed, no next test appointment made, no follow up on non-attendances.

Ensuring Operational, Data and System Set-up Integrity:

It is essential that the system and procedures are critically examined initially and routinely to ensure that the whole system integrity is maintained at all times.

This safety section is intended to highlight potential safety issues that must be understood and addressed before using the DAWN system.

It is vital for the on-going safe operation of your software that users of the software are aware of the Safety Instructions as detailed in this manual. Please keep this section of the manual in a safe place for ready referral by your staff.

The following section is split into the following areas below. Safety areas identified in all application areas are divided into one group, while separate anticoagulation and clinical

framework sections are listed below:

Safety Areas Identified for Clinical Framework Area:

- 1. What Safety Issues Are there?
- 2. Safety Check List for Adding/Editing Patient's Details
- 3. Safety Check List for Adding/Editing Patient Treatment Plan Details
- 4. Safety Check List for Adding Previous Treatment History
- 5. Safety Check List for Recording Medications and Their Doses
- 6. Safety Check List for Warnings And Contraindications

Safety Areas Identified for all Application Areas:

- Safety Check List for Adding/Editing/Deleting Letters/Messages
- 2. Safety Check List for Adding/Editing/Deleting Patient Questionnaires
- 3. Safety Check List for Clinic Settings
- 4. Safety Check List for Defining Procedures, Letters and Events
- 5. Safety Check List for Defining Look Up Information
- 6. Safety Check List for List View Settings
- 7. Safety Check List for Reports
- 8. Safety Check List for Questionnaire Definitions
- 9. Safety Check List for Data and Operational Integrity

3.1 What Safety Issues Are there?

The DAWN Rivaroxaban module provides the functionality to manage your non-VKA patients. The application allows for test results and specific details to be entered and examined to highlight any known contraindication or risk.

The application should be seen as an aid to the Healthcare Professional. It is a condition of use that all instructions or information issued by the application are checked by a competent healthcare professional before instructing the patient.



Inadequate reviewing of patient results and the next review date could cause severe injury or death.

Check that all medication dosages are correct before instructing the patient.

Develop written procedures to use with this system to meet your local needs.

These procedures should incorporate not only necessary operational steps

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but safety steps. The computer system along with these written procedures should form part of a quality management system. Subject this system to external auditing by a suitable quality standards authority.

Appoint a competent healthcare professional to carry out the patient monitoring.

Train staff in the use of the computer system.



Check that all non-attendees are followed up and every patient has a next review date.

DAWN Rivaroxaban module provides the use of List Views to aid in identifying the following:

- non-attendees
- patients with no next review date

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3.2 Safety Check List for Adding/Editing/Deleting Letters/Messages

- Ensure all new, altered and imported letters / message templates have been checked for correctness and have been thoroughly tested before using them in a live situation.
- Check the correctness of all letters/messages sent out from the system.
 This should be carried out for all available methods of communication including printed output, emails and faxes.
- To prevent the wrong information being communicated to a patient or healthcare professional, where possible, include the patient identifiers in any printed output, emails and faxes (e.g. dose instructions).
- To prevent the wrong dose instruction being communicated to a patient, include the current test date alongside the dose instruction.
- Where printing user letters/messages for a group of patients, have a tally of the number of user letters you expect to produce and match that to the number of user letters actually produced, to avoid missing anyone out.

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3.3 Safety Check List for Adding/Editing/Deleting Patient Questionnaires

- Ensure all new, altered and imported questionnaire types have been checked for correctness and have been thoroughly tested before using them in a live situation.
- When completing a patient questionnaire, check all the captured information is correct before confirming, saving or printing it.

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3.4 Safety Check List for Clinic Diary Settings

- Clinics may be added specially for review or induction of new oral anticoagulant agents or non-VKA with no timeslots or patient capacity set. Ensure that clinics are not over-booked.
- Care should be taken if sharing existing clinics between warfarin and non-VKA patient appointments so that too many patients are not assigned to one day.

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3.5 Safety Check List for Defining Procedures, Letters and Events

- Ensure all procedures have been defined correctly in the Procedure look-up table and have been made available for use by the relevant departments.
- Ensure all events have been defined correctly in the Event look-up table and have been made available for use by the relevant departments.
- Ensure all letters have been defined correctly (via message templates)
 and have been set up to be created on the appropriate message events.

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3.6 Safety Check List for Defining Look Up Information

 Ensure all information defined in the system look-up tables (like the Specific Risk of Prosthetic Heart Valve) has been entered and checked

for correctness.

 Check that any changes you make to Lookup Anticoagulation tables do not remove important warnings or restrictions from non-VKA patient records.

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3.7 Safety Check List for List View Settings

List views are interactive screens showing lists of patients meeting certain criteria and who require your attention today or this week *etc*. (See <u>Using List Views</u> topic for more details)

- Check that all the required list views have been set up correctly and are available for use.
- For each list view, check that the correct fields are displayed.
- For each list view, check that each filter brings up the correct patients and that no patients meeting the criteria are missing.

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3.8 Safety Check List for Reports

- Ensure all new, altered and imported reports have been thoroughly tested before using them in a live situation.
- Check that all the required reports have been defined and are available for use.
- For each report, check that the correct fields are included in the report.
- For each report, check that the correct data is being generated.

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3.9 Safety Check List for Questionnaire Definitions

If you have purchased and are using the questionnaire module:

- Ensure all new, altered and imported questionnaire definitions have been set up and checked for correctness. For each questionnaire definition:
 - Ensure the questionnaire definition has been correctly defined with the correct name and code and has been assigned to the

correct department.

- Ensure all the options / calculations have been defined correctly.
- Ensure all new, altered and imported questionnaire definition have been thoroughly tested in your practice system before using them in a live situation.

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3.10 Safety Check List for Data and Operational Integrity

Ensure you have written procedures and physical arrangements for:

- Checking all user profiles are properly set and are checked to be working
- Checking that the system settings are appropriate to the environment and method of working and to optimise system performance within your organisation.
- Taking a backup before you amend or delete settings from look-up and normal tables. Your procedure should also ensure that all other users refrain from making any other changes in the system until you have completed your amendments and verified they are correct. This will help minimise the potential loss of data should you inadvertently delete the incorrect settings and need to restore your database.
- Checking the hardware for possible errors, especially ensuring adequate disk space.
- Replacing backup media regularly media only has a set storage life.
- Backing up routinely at appropriate intervals and test if you are able to restore the data and programs if required.
- Ensuring your backup procedures are working and are appropriate for your database. If your database recovery type is set to full, ensure you are taking transaction log backups at regular intervals.
- Ensuring backup media is stored safely in a separate place from the computer system and is readily referenced.
- Providing adequate protection from:
 - o power failures, notebook/laptop battery discharge and interruptions.
 - staff inadvertently switching power off at the mains.

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- Checking for computer virus violation.
- Documenting and reporting software and operational problems or 'near misses' to DAWN Clinical Software and their own management.
- Documenting all changes to system set-up to show they are properly controlled and validated.
- Routinely checking that the DAWN Mailer program (for sending e-mails, networking printing or faxes) is operational and working correctly.
- Ensure your procedures are complete i.e. no sections have been removed, and are kept in a safe and accessible place for ready reference by your users. Make frequent checks that this is the case.
- Preventing and not allowing adding or editing of data in the underlying database by using a third party program or tool. All data access must be done through the DAWN Clinical Framework.
- Keeping all the application files complete and together. Do not copy
 files from previous copies of the application into the current set of files.
 The application files have a high inter-dependency and require absolute
 referential integrity.
- Encouraging use of the practice system to rehearse any infrequently used procedures before live execution.
- Using the practice system to test out future upgrades before applying the upgrade to the live system.
- Ensuring that users do not enter 'real or live' data into it your practice system and use it operationally.
- Ensuring any old, out of date user manuals or ebooks are destroyed and the current versions are readily available with no sections missing in full or in part.

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3.11 Safety Check List for Adding/Editing Patient Details

- When adding a new patient, the user should perform a search to ensure the patient's details have not been previously entered.
- Ensure all patient data (including all data entered via any of the tabs on the patient screen) has been entered and checked for correctness.
 Attention should be paid to the last name, first name, unit number and

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date of birth so that the patient can be uniquely identified every time.

- Ensure all patient procedures that are entered into the system have been checked for correctness.
- Ensure all patient events that are entered into the system have been checked for correctness.
- Ensure all patient reminders that are entered into the system have been checked for correctness.
- Ensure the patient has not been incorrectly marked as deceased or inactive.

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3.12 Safety Check List for Running Clinics / Monitoring Patient Results

- Ensure all entered laboratory results or other measurements are correct and have been entered against the correct patient with the correct test date.
- Check any contraindicated dose and always add a comment to say why the change was made.
- Validate each dose and next date BEFORE "informing the patient".
- If patient record books are being used, adopt checks to ensure each
 dosage instruction label is stuck into the correct patient's record book.
 For example, print patient identifiers such as name and number on
 each label and check the current label against previous ones in the
 book to ensure they match.
- Check dosing information is not copied by hand to the wrong book or patient report
- Check that all patients (including non attendees) due on a particular day have been dealt with completely.
- Check that the wrong information is not communicated to a patient by letter, telephone or any other communication method.
- Routinely ensure that all active patients have a future appointment.

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3.13 Safety Check List for Adding the Next Test Date/Time

Use the list view to ensure that all active patients have a next test date.

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3.14 Safety Check List for Adding/Editing Patient's Details

- When adding a new patient, the user should perform a search to ensure the patient's details have not been previously entered.
- Ensure all patient data (including all data entered via any of the tabs on the patient screen) has been entered and checked for correctness. Attention should be paid to the last name, first name, unit number and date of birth so that the patient can be uniquely identified every time.
- Ensure all patient procedures that are entered into the system have been checked for correctness.
- Ensure all patient events that are entered into the system have been checked for correctness.
- Ensure all patient reminders that are entered into the system have been checked for correctness.
- Ensure the patient's risk class, if applicable, has been correctly determined and selected.
- Ensure the patient has not been incorrectly marked as deceased or inactive.

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3.15 Safety Check List for Adding/Editing Patient Treatment Plan Details

- Ensure all treatment plan data (including all data entered via any of the tabs on the treatment plan screen) has been entered and checked for correctness. Attention should be paid to ensure:
 - the correct anticoagulant and dose has been chosen for the patient.
 - the correct primary diagnosis has been entered for the patient.

- the correct start date has been entered.
- if short term, the correct treatment duration in weeks and days has been entered.
- the correct phase of therapy was activated.
- the correct next test date and preferred clinic have been entered.
- Ensure the treatment plan has the correct status and has not been suspended or stopped in error.

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3.16 Safety Check List for Adding Previous Treatment History

- You MUST check that the historic results and notes have been entered correctly
- Correct next test date.

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3.17 Safety Check List for Recording Medications and Their Doses

 Check all drugs or medications, dosages and frequencies are recorded correctly before instructing the patient.

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3.18 Safety Check List for Warnings And Contraindication settings

Initiation Questionnaire Definitions

- Check all Initiation Questionnaires have been set up and checked for correctness. For each questionnaire:
 - Ensure required data may be correctly entered.
 For example a patient's renal or hepatic function can be recorded.
 - Ensure all the appropriate warnings to be triggered.
 You may need to add new rules if a new warning is reported.
 For example a patient over 80 years may not have certain doses set.
 - Ensure all contraindications are clearly marked as such.
 You may need to add new rules if a new contraindication is reported.

Regime settings

 Check all dose settings used in regimes to be accurate and to accommodate the required dosages.

Pre and Post Clinic (day) Checklists

• We recommend that each system manager organises a pre clinic or day checklist and a Post Clinic checklist based on the above checklists

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Part

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4 Customer Obligations

Customer Software Use Obligations

- The application should be seen as an aid to the healthcare professional. All
 dosage and review interval advice issued by the application must be
 checked by a competent healthcare professional before instructing the
 patient.
- 2. The customer must have a procedure to ensure **rigorous follow up of non attendees** and ensure that all patients have a next test date.
- **3.** The customer must ensure that only personnel that have been adequately trained in the use of the software should operate the system.
- 4. Prior to initial use and following any software upgrade or change to the software settings, a appropriate and thorough validation exercise of the software should be completed for your local way of working before 'live' operation. Records of the results of the validation shall be maintained. The validation should be authorised by the lead clinician/physician. A separate Test System which simulates live operation is highly recommended.
- 5. It is vitally important that the customer site establishes a robust method of backing up and restoring their data, including occasional tests of the backups through restoration. Usually the backup should be done at the end of each working day. If there is a lot of system activity a more frequent back-up procedure should be considered.
- 6. The customer is expected to operate best practice with regard to using pre and post-clinic checklists and keeping their copy of the software up to date. The product is being periodically updated with important safety and operational features. If you are paying software maintenance fees these upgrades are usually free.
- 7. The customer is expected to keep abreast of key changes and urgent issues in the product and documentation by visiting the webpage http://www.4s-DAWN.com/DAWNSafetyNotices.htm weekly. To this end, the customer must inform 4S of changes to lead contact personnel to ensure that communication is not missed.
- **8.** The customer shall review / update the settings (such as questionnaires) and operation of the software on any change to best practise or new advice from drug manufacturers or other relevant bodies.
- **9.** The customer should notify 4S immediately if they notice any anomalies within the data or experience anything within the system that could potentially cause a mishap.

Version 1.0

Part

5 Overview of Novel Oral Anticoagulants Module

Features of software to support monitoring of anticoagulation with new oral anticoagulant agents (non-vitamin K antagonists) include

Non-VKA list view for easy management of scheduled reviews

Integrated non-VKA history and warfarin treatment records within the patient record

<u>Structured questionnaire</u> approach to check for contraindications / interactions / risks

Help to follow the recommended prescribing guidelines

Powerful reporting on patient outcomes and population data

Able to provide support separately for <u>other agents</u> besides Rivaroxaban through specifically-designed questionnaires for each agent

The DAWN non-VKA module for Rivaroxaban provides structured questionnaires based on the recommended use of the anticoagulant and these include questionnaires for **Initiation** of anticoagulation and for routine **Follow-up**. Completion of the questionnaires can be scheduled for future dates so that the user can keep track of patients started on Rivaroxaban or due for a change to Rivaroxaban anticoagulation.

This software should be seen as an aid to the Healthcare Professional. It is a condition of use that all instructions or information issued by the application are checked by a competent healthcare professional before instructing the patient.



Inadequate reviewing of patient instructions and the next review date could cause severe injury or death.

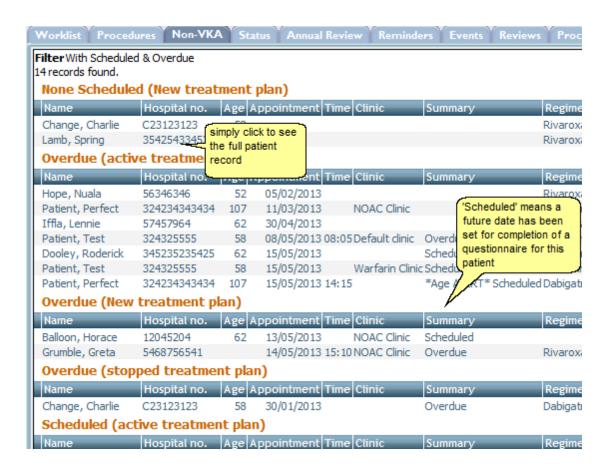
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Contact 4S DAWN Clinical Software for more information at sales@4s-DAWN.com / support@4s-DAWN.com / su

5.1 Non-VKA list view

DAWN Rivaroxaban module presents a list of patients for review today / this week / this month. Each patient can have Initiation or Follow-up questionnaires scheduled for future dates.

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The list of patients may be filtered by date of next follow-up / clinic location / risk class / patient group / diagnosis.

Click on the filters on the left of the list view screen to tailor the list you wish to view.



The Patient Search and Reports screens also provide searches on your DAWN database for patients on different anticoagulants.

(Overview page)

(Detailed Workflow page)

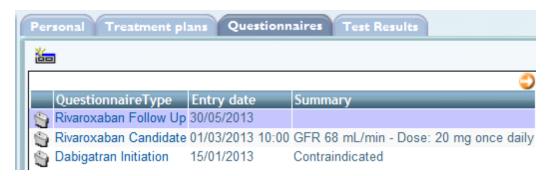
(Back to Workflows in DAWN page)

5.2 Integrated non-VKA / VKA patient record

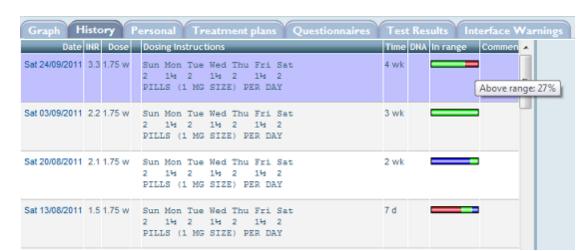
The DAWN patient record accommodates treatments with warfarin and non-VKAs like Rivaroxaban. Each patient has a treatment plan when they start a particular anticoagulant treatment. The treatment plan defines the key elements of the treatment such as dose, duration, *etc.*



For Rivaroxaban the anticoagulation history is accessed from the 'Questionnaire' tab -



(See below for full questionnaire screen.)



For Warfarin, the 'History' tab shows details of the INR and dose history -

(Overview page)

5.3 Questionnaires for non-VKA therapy management

Two structured questionnaires help you record all relevant details at the time Rivaroxaban is **Initiated** or on **Follow-up** reviews for your Rivaroxaban patient -

Initiation Questionnaire

This questionnaire helps to determine whether the patient is a suitable candidate for Rivaroxaban, and if so, what the appropriate dose of Rivaroxaban is.

Follow-up Questionnaire

This questionnaire can be used to audit whether the patient is taking the medication correctly and whether they have experienced any problems at all.

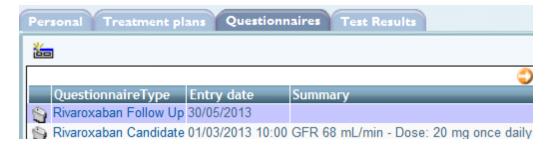
The questions cover

- Indications for Rivaroxaban therapy
- renal function including a calculator for Cockcroft-Gault estimate of CrCl
- records for other tests
- Contraindicated or Interacting drugs including other anticoagulants or platelet inhibitors
- a reminder to ensure INR is not too high if switching from a vitamin K antagonist
- Contraindicated conditions and Haemorrhagic Risks
- records for CHA₂DS₂VASc and HASBLED scores as appropriate
- notes for planned procedures or other comments
- Rivaroxaban dose



4 You should ensure that the questionnaire content is appropriate for the current recommendations drug manufacturer.

A Follow-up may be scheduled for patients starting on Rivaroxaban and the history for questionnaires is easily viewed on the Questionnaires tab -



Patient details will appear on your Non-VKA list view when the date of the next follow-up is due.

(back to Overview page)

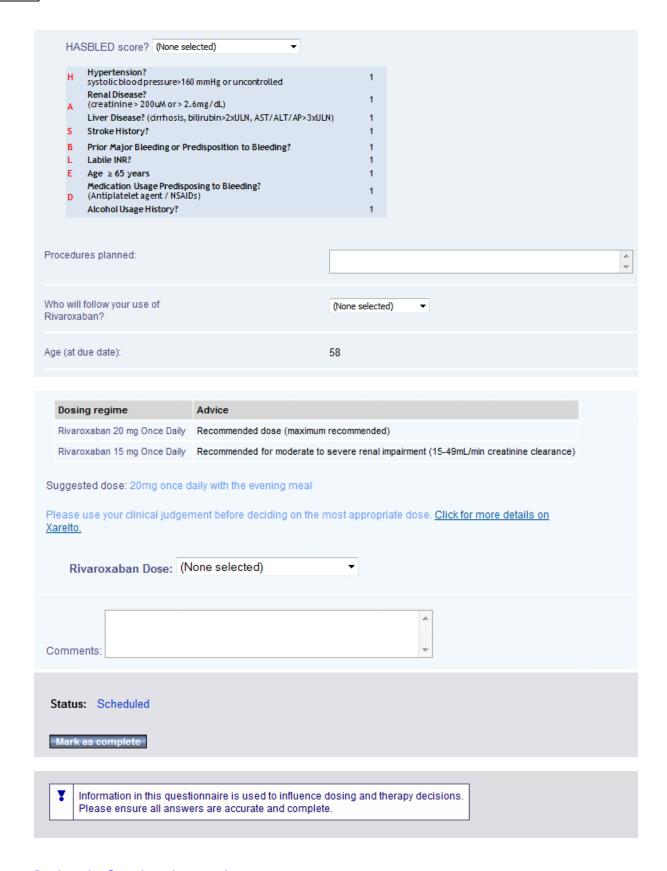
(back to Settings for Regime and Dose Settings page)

5.3.1 Rivaroxaban Initiation Questionnaire



If switching from VKA, is the INR still elevated?	Delay starting Rivaroxaban (until INR<3.0 for AFNV	
	*		
Date of first Rivaroxaban dose:			
Measured Creatinine Clearance: mL/min	Age (at due date):	58	
eGFR: mL/min	Gender:	Male	
Serum Creatinine: µmoVL	Body Weight:	kg	
1.23 x (140 -age years) x weight kg (x 0.85 if female) serum creatinine µmol/L Calculate Cockcroft-Gault CrCl Cockcroft D, Gault MD. Nephron, 16:31-41, 1976			
Please be aware of the limitations of estimates of renal function in relation to muscle mass, race and diet. Click to refer to dosing guidance with renal impairment			
Other Tests:		A	
The following lists are for guidance only and are not exhaustive. Please use your clinical judgement before decision making. <u>Click for more details on Xarelto</u>			
Contraindicated Drugs*:	OTHER ANTICOAGULANT (HE DRONEDARONE ITRACONAZOLE KETOCONAZOLE POSACONAZOLE RITONAVIR SINTHROME WARFARIN	EPARIN, DABIGATRAN,)	
Interacting drugs*:	☐ ASPIRIN ☐ CLARITHROMYCIN ☐ OTHER NSAIDS ☐ TELITHROMICIN		

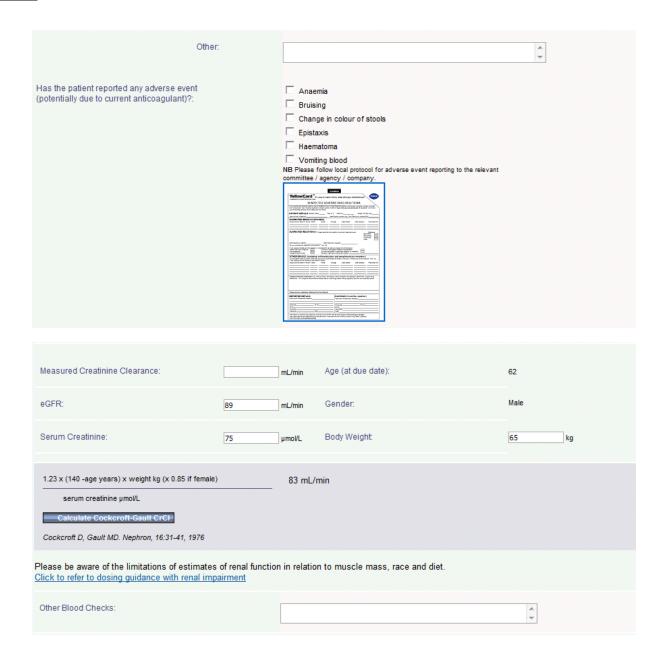
Other anticoagulant or platelet inhibitor*: Care is to be taken if patients are treated concomitantly with medicinal products affecting haemostasis	☐ Abciximab ☐ Eptifibatide ☐ Prasugrel ☐ Ticagrelor ☐ (Other)
If (other), please give details:	
* These lists are for guidance only and are not exhaustive. Ple Click for more details on Xarelto	ease use your clinical judgement before decision making.
Other contraindications*:	 □ Clinically significant active bleeding □ Creatinine clearance <15ml/min □ Hepatic impairment or liver disease expected to have any impact on survival □ Hypersensitivity to tablet excipients or galactise intolerance □ Paediatric Patient □ Pregnancy and breastfeeding □ Prosthetic Heart Valve
Haemorrhagic Risks*	Active ulcerative gastrointestinal disease Bronchiectasis or history of pulmonary bleeding. Congenital or acquired coagulation disorder Intraspinal or intracerebral vascular abnormalities Recent brain, spinal or ophthalmological surgery Recent intracranial or intracerebral haemorrhage Uncontrolled severe arterial hypertension Vascular retinopathy
* These lists are for guidance only and are not exhaustive. <u>Click for more details on Xarelto</u>	. Please use your clinical judgement before decision making.
CHADS ₂ score? (None selected) ▼	
C Congestive heart failure	1
H Hypertension (or treated hypertension)	1
A Age older than 75 years	1
D Diabetes mellitus	1
S Previous stroke or transient ischaemic attack	2



(back to the Questionnaires page)

5.3.2 Rivaroxaban Follow-up Questionnaire

Rivaroxaban Follow Up			р	
Patient Name:	Horace Balloon	Date of completion:	31/05/2013 16:00 31/05/2013 at: 16 : 00 24hr format NB Please check this appointment is made in your clinic diary or hospital administration system.	
NHS Number:		to be completed at	NOAC Clinic ▼	
Unit No:	12045204	Status	Scheduled	
Therapeutic Indication: Atrial fibrillation nonvalvular NB Remember to schedule a follow-up questionnaire for this patient 6 months after the Rivaroxaban treatment plan is activated				
I have taken the correct dose	e every day	C No C Yes		
I might have taken too many		C No C Yes		
I might have missed one or	more doses	C No C Yes		
I have started a new medica	Notes:	C No C Yes	A	
Reasons for compliance pro		Dementia Fear of side-effects Gastrointestinal Bleed Lack of information Lives alone Multiple medications Prescriptions from several doc	ctors	



Contraindicated Drugs*:	OTHER ANTICOAGULANT (HEPARIN, DABIGATRAN,) DRONEDARONE ITRACONAZOLE KETOCONAZOLE POSACONAZOLE RITONAVIR SINTHROME WARFARIN
Interacting Drugs*:	ASPIRIN CLARITHROMYCIN OTHER NSAIDS TELITHROMICIN VORICONAZOLE
Other anticoagulant or platelet inhibitor* :	Abciximab Eptifibatide Prasugrel Ticagrelor (Other)
If (other), please give details:	A
Other contraindications*:	 Clinically significant active bleeding Creatinine clearance <15ml/min Hepatic impairment or liver disease expected to have any impact on survival Hypersensitivity to tablet excipients or galactise intolerance Paediatric Patient Pregnancy and breastfeeding Prosthetic Heart Valve
Haemorrhagic Risks:* *This list is for guidance only and is not exhaustive. Please use your clinical judgement before decision making.	Active ulcerative gastrointestinal disease Bronchiectasis or history of pulmonary bleeding. Congenital or acquired coagulation disorder Intraspinal or intracerebral vascular abnormalities Recent brain, spinal or ophthalmological surgery Recent intracranial or intracerebral haemorrhage Uncontrolled severe arterial hypertension Vascular retinopathy
* These lists are for guidance only and are not exhaustive Click for more details on Xarelto	e. Please use your clinical judgement before decision making.

If (all an) along of the data the			
If (other), please give details:			
Other contraindications*:		☐ Clinically significant active bleeding ☐ Creatinine clearance <15ml/min ☐ Hepatic impairment or liver disease expected to have any impact on survival ☐ Hypersensitivity to tablet excipients or galactise intolerance ☐ Paediatric Patient ☐ Pregnancy and breastfeeding ☐ Prosthetic Heart Valve	
Haemorrhagic Risks:*		Active ulcerative gastrointestinal disease Bronchiectasis or history of pulmonary bleeding. Congenital or acquired coagulation disorder Intraspinal or intracerebral vascular abnormalities Recent brain, spinal or ophthalmological surgery	
* This list is for guidance only and is not exhaust use your clinical judgement before decision makin	ive. Please 1g.	Recent intracranial or intracerebral haemorrhage Uncontrolled severe arterial hypertension Vascular retinopathy	
* These lists are for guidance only an Click for more details on Xarelto	d are not exhaustive. Plea	ease use your clinical judgement before decision making.	
Rivaroxaban Dose: Rivaroxaban 20 mg Once Daily Suggested dose: 20mg once daily with the evening meal			
Please use your clinical judgement be Xarelto.	fore deciding on the most a	appropriate dose. Then update the treatment plan as required. Click for more	details on
Dosing regime Advice			
	d dose (maximum recommended	ed)	
Rivaroxaban 15 mg Once Recommende clearance)	d for moderate to severe renal i	I impairment (15-49mL/min creatinine	
Comments:		A	
Status: Scheduled Mark as complete			
Information in this questionnair Please ensure all answers are		ng and therapy decisions.	

(back to the Questionnaires page)

5.4 Help to follow recommended (SmPC - Summary of Product Characteristics) guidelines

In this section, the software alerts and dose recommendations are explained. DAWN has settings for drug-specific contraindications and approved dosing regimes which are used within the patient treatment plan and questionnaire to help the user adhere to the chosen guideline. The settings for risks, warnings and contraindications may be updated so that every review of the patient's anticoagulation is fully informed from the latest guidance.

DAWN will highlight the following on the questionnaire screen

Contraindicated concomitant drugs or conditions including impaired renal function

Warnings on inconsistency and completeness based on advanced age

Dose warnings on discrepancies in the recorded details

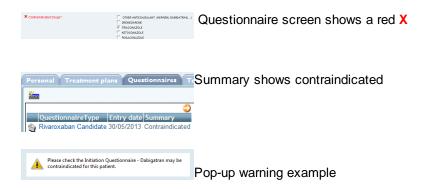
The system also performs some <u>validation checks</u> and highlights any discrepancies when the user activates a new non-VKA treatment plan.

(click here to go back to Overview page)

(back to FAQs page)

5.4.1 Contraindications

Contraindications are highlighted in RED on the Initiation Questionnaire and shown on the Questionnaires tab summary comment. Pop-ups will also highlight contraindications on attempting to proceed with a plan for Rivaroxaban.



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The settings for contraindications may be updated as new medical evidence emerges using the Look Up Tables in DAWN.

(back to Help page)

5.4.2 Renal function

Renal impairment may affect the appropriate anticoagulant or dose and renal function may be recorded as measured creatinine clearance, estimated GFR or the Cockcroft-Gault estimation of creatinine clearance. DAWN provides a calculator for the Cockcroft-Gault estimation from serum creatinine and body weight.



(back to Help page)

5.4.3 Warnings on inconsistency and completeness

 ${\bf Warnings}$ are shown for the ${\bf \underline{Suggested\ dose}}$ on the Rivaroxaban Initiation Questionnaire for age / renal impairment / other warnings.

Suggested dose: Rivaroxaban is contraindicated according to information recorded above.

CONTRAINDICATED Use is not recommended

On activating a treatment plan for Rivaroxaban, several checks are made in the background and an error will highlight any discrepancy.

For example, DAWN will

check that the patient has an appropriate Primary Diagnosis and highlight any not recognised as

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therapeutic indications for the anticoagulant.

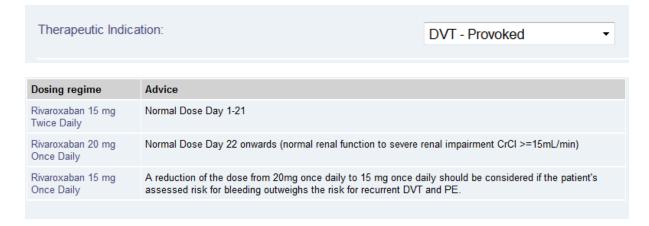
- check that the user has completed a Rivaroxaban Initiation Questionnaire listing drugs, conditions and test results.
- check the dose of Rivaroxaban is advised for the Primary Diagnosis.

The settings for warnings may be updated as new medical evidence emerges using the Look Up Tables in DAWN.

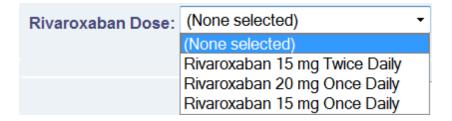
(back to Help page)

5.4.4 **Dosing warnings**

Dose options are clearly presented on DAWN for the patient's indication -



The user chooses the dose from a drop-down menu -



The dose is assigned for each patient using the Initiation Questionnaire and this links to the patient's treatment plan which must have the dose and Primary Diagnosis set as indicated in the questionnaire. If there is a discrepancy in the information entered for your patient, a warning is displayed on screen.



The settings for dose options may be updated as new medical evidence emerges using the Look Up Tables in DAWN.

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(back to Help page)

5.4.5 Overview of Validation Checks

Activation of a new treatment plan for non-VKA on DAWN triggers some background checks as follows.

activate

If the user selects 'activate' and all checks pass the treatment plan is activated without error. If there is any discrepancy, an error message will indicate the problem and the user may correct the Initiation Questionnaire or the treatment plan or both and activate again. Should your DAWN settings need to be updated as new medical evidence emerges, please contact your system administrator.

Checks for non-VKA treatment plans -

• the primary diagnosis is one known to be acceptable for the chosen drug and dose

For example, you may have chosen 15mg twice daily for Rivaroxaban in an AF patient. If this regime is not permitted, it will not be possible to complete an Initiation Questionnaire with this combination and a treatment plan cannot be activated and a follow-up cannot be scheduled.

DAWN AC performs 2 checks on every primary diagnosis. Firstly, the drug and diagnosis must be stored in your Look Up Tables as a Therapeutic indication like Rivaroxaban being acceptable as an anticoagulant in Atrial Fibrillation (non-valvular). Secondly, DAWN stores 'Permitted Regimes' for each diagnosis. So, several doses such as 15mg once daily or 20mg once daily may be acceptable but 15mg twice daily may not be acceptable for Rivaroxaban in Atrial Fibrillation (non-valvular).

the drug chosen is not a VKA anticoagulant

For example, you may have chosen Warfarin mixed tablets regime and marked the treatment plan as non-VKA in the target range box.



You have selected a Non-Vitamin K Antagonist Target Range for an anticoagulant that is a Vitamin K Antagonist

the appropriate questionnaire has been completed BEFORE the treatment plan is activated

For example, you may select a treatment plan for Rivaroxaban 20mg once daily but forget to go through the list of possible contraindications / interactions / risks. DAWN will prevent activation of the treatment plan and scheduling any follow-up until the guestionnaire is completed.

The requirement for a questionnaire is set in the Look Up Table called 'Questionnaire settings' and may be updated by your system administrator to add any required questionnaires for particular drugs.

the completed questionnaire has the same details as the treatment plan

For example, you may select a treatment plan for Rivaroxaban 20mg once daily on the Initiation Questionnaire but choose Rivaroxaban 15mg once daily on the treatment plan.



You have selected a regime for 15 mg once daily but the Initiation Questionnaire records the intended dose as 20 mg once daily. Please correct the regime or amend the recommendation in the initiation questionnaire and include a comment to say why you are changing it.

(back to Help page)

(back to Settings for Regime and Dose Settings page)

5.5 Reporting on the non-VKA patient database

The powerful SQL reporting tools in DAWN can be configured to extract counts or lists of patients on certain anticoagulants. These reports may be used to assess recorded events in relation to the anticoagulant used.

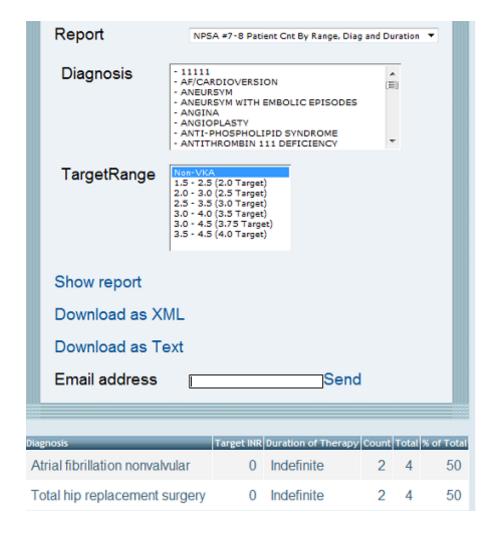
Example 1 Patient count by range, diagnosis and duration

Example 2 Events - all areas

(click here to go back to Overview page)

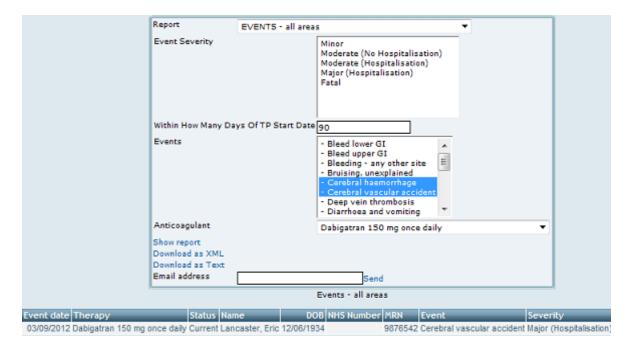
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5.5.1 Example 1



(back to reporting page)

5.5.2 Example 2



(back to reporting page)

5.6 Other Non-VKA agents / Questionnaires

Please note this module can provide support separately for other agents besides Rivaroxaban through specifically-designed questionnaires for each agent. Please call for a quotation.

Also, future releases for the DAWN Rivaroxaban module are planned to include a questionnaire for perioperative situations.

Contact 4S DAWN Clinical Software for more information at sales@4s-DAWN.com / support@4s-DAWN.com / support@4s-DAWN.com / sales@4s-DAWN.com / support@4s-DAWN.com / sales@4s-DAWN.com / <a href

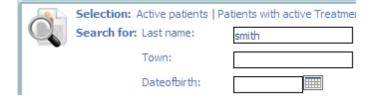
(click here to go back to Overview page)

Part

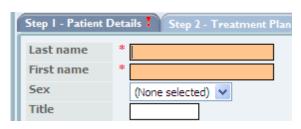
6 Detailed Workflow

The following workflow describes how to add and deal with a new patient on non-VKA therapy or edit an existing warfarin patient so that are logged as being on non-VKA therapy. The essential steps in recording non-VKA anticoagulation are as follows -

 Check if the patient details are already on DAWN (see <u>patient</u> <u>search</u>)



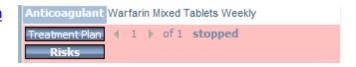
2. Add the patient details (identification numbers, name and address, etc) or update a previous record as required



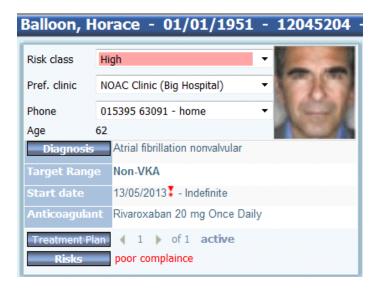
3. Complete an <u>Initiation</u> Questionnaire



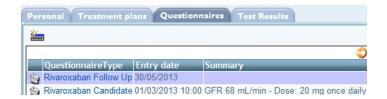
4. Stop any existing treatment plan (for other anticoagulant or dose)



5. Activate a treatment plan for the chosen anticoagulant and dose



6. Schedule the next follow-up as a Follow Up Questionnaire



7. See the <u>FAQs page</u> for some common queries on the Non VKA Workflow



Don't forget to chase patients due for follow-up at regular intervals! - you'll find them listed on the list view for Non-VKA.

At some time you may need to -

Change the dose of anticoagulant

Switch to a different anticoagulant

Stop the current anticoagulation record

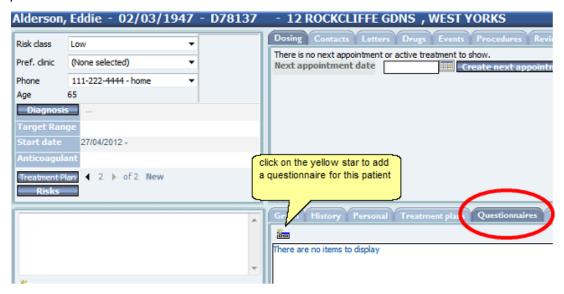
Mark the patient as inactive / deceased

In order to keep track of all your patients, you will need to follow the <u>daily / weekly routines</u> to check for patients overdue for follow-up or not yet actively treated.

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6.1 Initiation Questionnaire

For anticoagulants such as Rivaroxaban, you may wish to always complete an Initiation Questionnaire before activating a treatment plan on DAWN. You can add a Rivaroxaban Initiation Questionnaire to any patient from the Questionnaires tab.



The 'Due Date' will default to today but you can change this if you wish. If you are not ready to answer all the questions, simply click OK and the details may be completed later.

The questions cover

Indications for Rivaroxaban therapy

Renal function including a calculator for Cockcroft-Gault estimate of CrCl

Contraindicated or Interacting drugs including other anticoagulants or platelet inhibitors

A reminder to ensure INR is not inappropriately elevated if switching from a vitamin K antagonist

Contraindicated conditions and Haemorrhagic Risks

Records for CHA2DS2VASc and HASBLED scores

Notes for planned procedures or other comments

Rivaroxaban dose

Once you have answered all sections, click on 'Mark as complete' at the bottom of the questionnaire.

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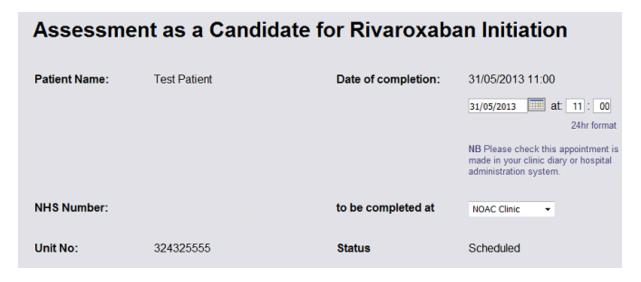
(back to Integrated non-VKA / VKA patient record)

(back to Detailed Workflow page)

(back to Settings for Regime and Dose Settings page)

6.1.1 Schedule an Initiation (non-VKA)

On adding an Initiation Questionnaire, change the 'Due Date' to the date you will complete the details.



Click OK at the bottom of the Questionnaire screen to save this Initiation with the scheduled date.



You will find the questionnaire on the questionnaires tab for later completion.



6.1.2 Complete an Initiation Questionnaire

The Initiation questionnaire is structured to help you record all relevant details at the time Rivaroxaban therapy is started. See details of the Initiation Questionnaire.



If you cannot answer some questions, simply click OK or Save and come back later to complete the answers.

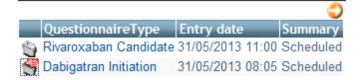
Mark as complete

On marking the answers as complete you are confirming that DAWN can store this record, display a summary on the questionnaires tab and check details against the treatment plan.

If you've added some details in error, Cancel your changes using 'Cancel' or the rewind button at the top of the screen -



If you need to delete a questionnaire completely, look for the bin symbol on the questionnaires tab and save before confirming you wish to delete this record-



If you need to add more information or adjust the Initiation Questionnaire which is already completed -

- 1. locate the completed questionnaire on the Questionnaires tab
- 2. select Unlock to edit

Unlock to edit

3. save your changes

NB - unlocking a previous questionnaire to edit it may cause the details to be updated with subsequent changes to the patient details. For example, if the patient was previously on an interacting drug which was later removed from your DAWN database, the drug would still be stored in the old completed questionnaire. On unlocking the old questionnaire, the record for this drug may no longer be available.

(back to Initiation Questionnaire page)

6.1.2.1 Therapeutic Indication

The dropdown menu for **Therapeutic indication** displays options for the primary diagnosis. The available options are those set for any anticoagulant in the Lookup Tables as 'Therapeutic Indications'.

Selection of the most relevant therapeutic indication for your patient is recommended. If you are unsure, you might wish to complete this later.



See Lookup Tables to adjust the options displayed in this dropdown.

(back to Initiation Questionnaire page)

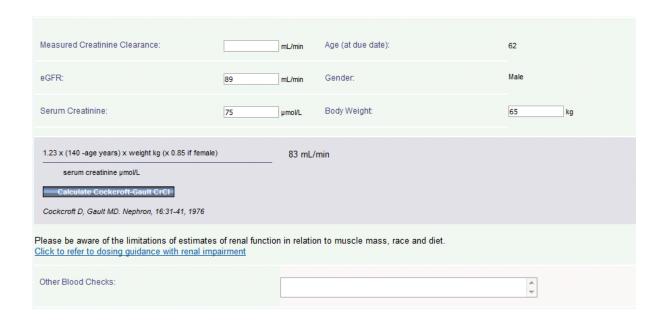
(back to Settings for New Oral Anticoagulants page)

6.1.2.2 Renal function

Estimates of renal function may be recorded in several ways on the Initiation Questionnaire and these will be used to modify the suggested dose where renal function is severely impaired or not recorded.

- measured creatinine clearance (laboratory estimation)
- Estimated Glomerular Filtration Rate (eGFR)
- serum creatinine
- Cockcroft-Gault estimation of creatinine clearance
- other measures may be recorded in the notes box

DAWN provides a calculator for estimating renal function from serum creatinine and body weight. Enter these 2 values and click on the 'Calculate Cockcroft-Gault CrCL'.



Note - if you have a laboratory estimation which is less than a numeric value (like <10), please enter the number (like 10) in the Measured Creatinine Clearance, eGFR or Serum Creatinine boxes. Similarly for results which are reported as greater than a value (like > 220), please enter the numeric value (like 220). The limits used for renal impairment are set as follows in DAWN -

- Severe renal failure is defined as measured creatinine clearance or estimated glomerular filtration rate or Cockcroft-Gault estimation of CrCl less than 15mL/min.
- If more than one measure of renal function is entered, measured creatinine clearance is considered in preference to estimated glomerular function rate in preference to Cockcroft-Gault estimation of creatinine clearance
- Moderate to severe renal impairment is defined as measured creatinine clearance = 15-50 L/min or estimated glomerular filtration rate = 15-60 mL/min or Cockcroft-Gault estimation of CrCl = 15-50 /min

The DAWN system alerts you if you add an unusually low or high serum creatinine or body weight measurement. If you get a warning message, please check the details you entered carefully.

(back to Initiation Questionnaire page)

6.1.2.3 Contraindicated drugs

Some concomitant drugs may be known to be contraindicated for the chosen anticoagulant as published in the prescribing guidelines. Please tick any drugs if your patient is currently prescribed this drug.

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OTHER ANTICOAGULANT (HEPARIN, DABIG	ATRAN,)
DRONEDARONE	
TRACONAZOLE	
KETOCONAZOLE	
POSACONAZOLE	
RITONAVIR	
SINTHROME	
WARFARIN	

The list of drugs displayed are defined in the Look Up Tables on your DAWN database and additional drugs may be added to this list as required. Please contact your system administrator to add new drug settings to the 'Interacting Drugs' table.

(back to Initiation Questionnaire page)

(back to FAQs page)

(back to Interacting Drugs Settings page)

6.1.2.4 Interacting drugs

Some interacting drugs may be known to be increase the haemorrhagic risk if used along with the chosen anticoagulant. See relevant published prescribing guidelines. Please tick any drugs if your patient is currently prescribed this drug.

ASPIRIN	
CLARITHROMYCIN	
OTHER NSAIDs	
TELITHROMICIN	
VORICONAZOLE	

(back to Initiation Questionnaire page)

(back to Interacting Drugs Settings page)

6.1.2.5 Other anticoagulant or platelet inhibitor

It is important to record any other anticoagulant or platelet inhibitor prescribed along with Rivaroxaban even if this for a short period.

Other anticoagulant or platelet inhibitor*: Care is to be taken if patients are treated concomitantly with medicinal products affecting haemostasis	Abciximab Eptifibatide Prasugrel Ticagrelor (Other)
If (other), please give details:	^ +

The list of drugs displayed may be added to or edited in the General Lookup Category for 'Anticoagulant or Platelet Inhibitors' - please contact your system administrator to arrange changes to the displayed options.

(back to Initiation Questionnaire page)

6.1.2.6 Switching from VKA

If your patient is switching from warfarin (or other vitamin K antagonist) to Rivaroxaban, please check the latest INR result and tick the box if it is above the recommended limit.

If switching from VKA, is the INR still elevated? □	Delay starting Rivaroxaban until INR<3.0 for AFNV
▲	Delay starting Rivaroxaban until INR<2.5 for DVT and prevention of recurrent DVT and PE

(back to Initiation Questionnaire page)

6.1.2.7 Other contraindications

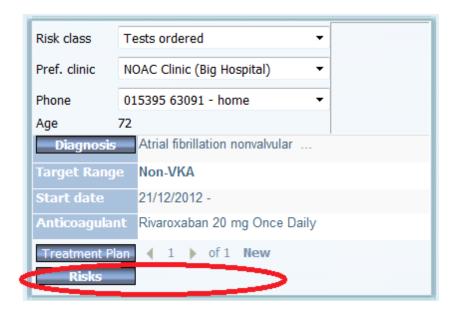
Please tick any of the other contraindications which apply to your patient. These risks are identified in prescribing guidelines as contraindications for dosing with Rivaroxaban.

Other contraindications*:	Clinically significant active bleeding
	Creatinine clearance <15ml/min
	Hepatic impairment or liver disease expected to have any impact on survival
	Hypersensitivity to tablet excipients or galactise intolerance
	Paediatric Patient
	Pregnancy and breastfeeding
	Prosthetic Heart Valve

The list of contraindications displayed on the Initiation Questionnaire may be edited / added to by your system administrator using the Look Up Tables called Risks and Specific Risks.

NB - any risks identified on the Initiation Questionnaire will **NOT** automatically display at the top-left of your patient screen. You may wish to highlight these manually on the patient screen either by <u>adding</u> Risks for a new patient or clicking on the 'Risks' button to add risks for an existing patient screen.

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(back to Risk Settings page)

6.1.2.8 Haemorrhagic risks

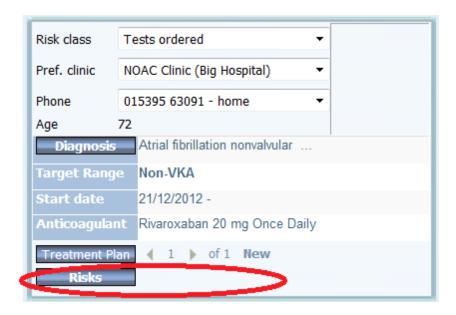
Please tick any of the risks which apply to your patient. These risks are identified in prescribing guidelines as significant risks for consideration in dosing decisions for Rivaroxaban.

Haemorrhagic Risks*	Active ulcerative gastrointestinal disease Bronchiectasis or history of pulmonary bleeding. Congenital or acquired coagulation disorder Intraspinal or intracerebral vascular abnormalities Recent brain, spinal or ophthalmological surgery Recent intracranial or intracerebral haemorrhage Uncontrolled severe arterial hypertension Vascular retinopathy

The list of haemorrhagic risks may be edited / added to by your system administrator using the Look Up Tables called Risks and Specific Risks.

NB - any risks identified on the Initiation Questionnaire will **NOT** automatically display at the top-left of your patient screen - see <u>adding Risks for a new patient</u> section or click on 'Risks' button to add risks on the patient screen.

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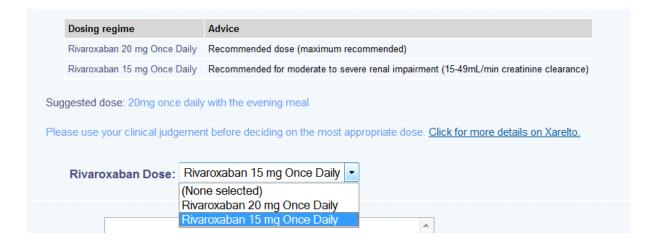


(back to FAQs page)

(back to Risk Settings page)

6.1.2.9 Rivaroxaban Dose

The dose recorded on the Initiation Questionnaire may be chosen from any regime for this anticoagulant on DAWN.



This screen shows advice for permitted regimes set for the chosen Therapeutic Indication (at the top of this questionnaire). To update or change the displayed options, request that your system administrator edits the settings for Anticoagulation Tables.

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6.1.2.10 CHADS and HASBLED scores

CHADS2 and HASBLED scores may be optionally recorded form the dropdown menus on your questionnaire.



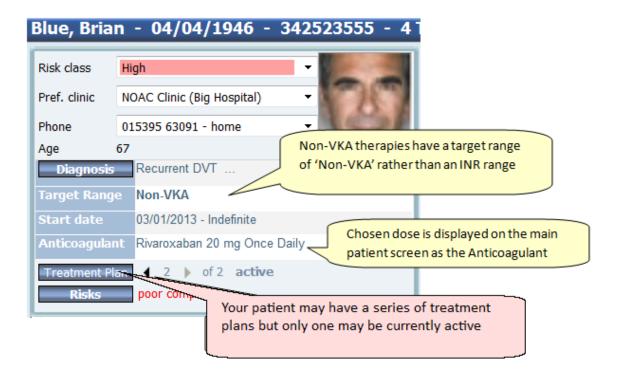


The dropdown options are provided from the settings in your DAWN Normal Tables, General Lookup Category (CHADS2 Score and HASBLED). You may wish to request that your system manager updates the options available.

(back to Initiation Questionnaire page)

6.2 Non-VKA treatment plan

Non-vitamin K antagonist therapy is recorded on DAWN using a new treatment plan.



Any significant change in the patient's anticoagulation management should be recorded by stopping the existing treatment plan and starting a new treatment plan.

NB – DAWN will prevent a change of anticoagulant within an active treatment plan and require any existing treatment plan to be stopped.

DAWN provides INR and dosing screens for VKA (like warfarin) and questionnaires for non-VKA management. Each Questionnaire can be scheduled in advance and completed to store the important information for your patient. Complete all sections and mark as complete.

See sections on changing treatment plan / stopping a treatment plan / <u>starting a treatment plan for a new patient</u> / <u>viewing patient history</u>.

(back to Detailed Workflow page)

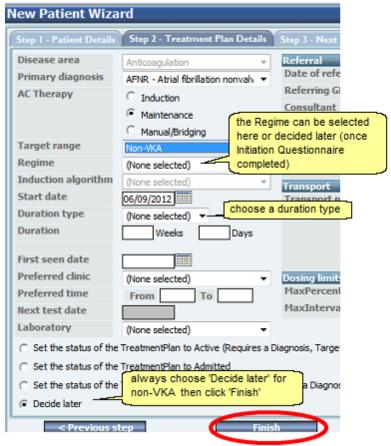
6.2.1 Starting a non-VKA treatment plan

The steps to starting a treatment plan for your patient on DAWN are outlined below as are the essential information you need for the treatment plan.

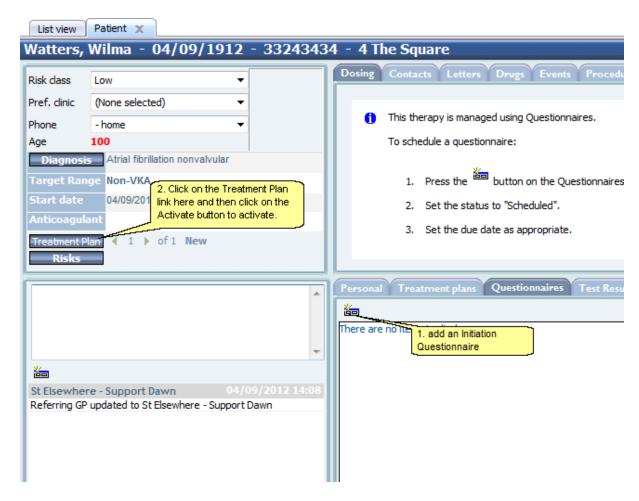
STEPS -

1. Add your patient to DAWN (see how to add a patient record) AND add an initiation questionnaire. If your patient already has a record on DAWN, ensure any other anticoagulation treatment plan is stopped and click on Treatment Plan and 'New' to add a new treatment plan.

If your patient has no record on DAWN, the New button on the Patient Search screen will take you to the following 'New Patient Wizard screen.



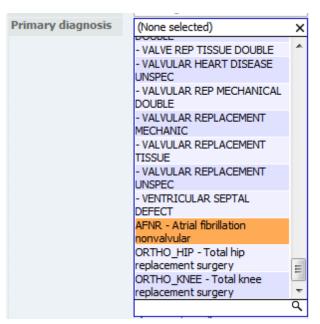
2. Activate a treatment plan



3. Schedule a Follow-up questionnaire

The essential choices on a DAWN treatment plan are

 Primary diagnosis - must be listed as a therapeutic indication for the non-VKA anticoagulant agent (contact your system administrator if you have problems activating your treatment plan).



- Target range must be 'non-VKA' for non vitamin K antagonists
- Regime choose the dose



• **Duration type** - short term requires a duration / long term has no duration

The treatment plan may not be activated without these selections but, if you do not have the details at hand, you can save the treatment plan and activate it later.

(back to Detailed Workflow page)

(back to FAQs page)

6.2.2 Changing a non-VKA treatment plan



It is strongly recommended that you stop the treatment plan and start a new treatment plan for any significant change in the patient's anticoagulation.

For example,

changing dose from 20mg once daily to 15mg once daily

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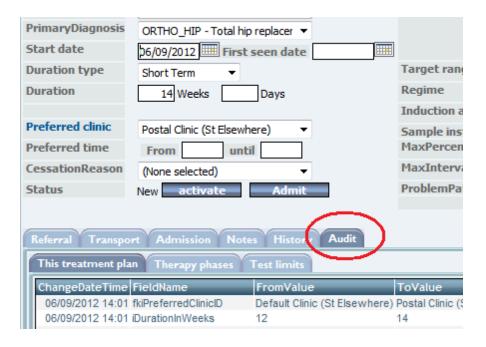
or

• changing the reason for anticoagulation



For changes such as a change to clinic or duration of treatment, click on Treatment plan to edit and save your changes.

Any changes to the treatment plan will be audited in the 'Audit' tab on the Treatment Plan screen like this -



(back to Detailed Workflow page)

6.2.3 Stopping a non-VKA treatment plan

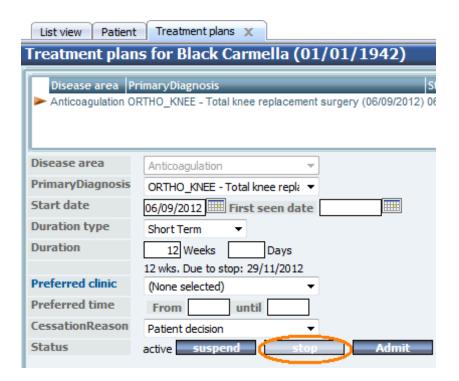
For any significant change to a patient's anticoagulation, such as changing drug or restarting after a period on different or no anticoagulation, please stop the treatment plan and start a new treatment plan.

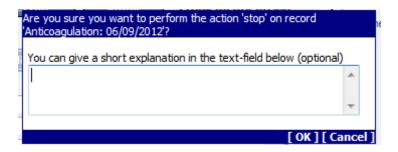
- 1. click on Treatment plan on the Patient screen
- select a Cessation reason mandatory only if cessation reasons are available on your DAWN database.

(this option may not be set up for your DAWN AC system)

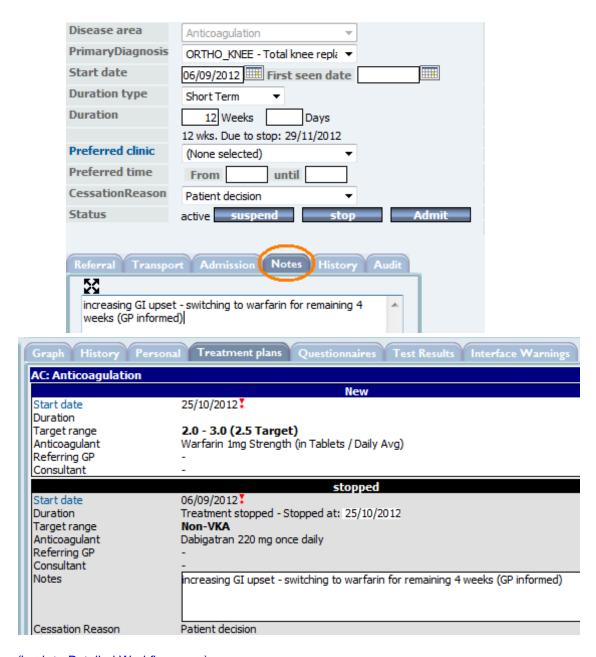
- 3. click on stop
- 4. click on OK to the pop-up box.

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Hint - add relevant details in the Notes tab as they will be easily viewed later on the Treatment Plans tab of the main patient screen like this.



(back to Detailed Workflow page)

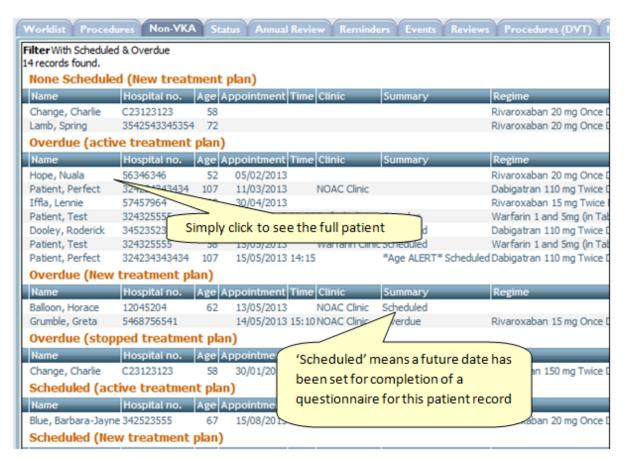
6.3 Follow-up Questionnaire

To review the dose for a patient on Rivaroxaban or other non-VKA agent, locate the patient record using either the search facility or the list view.



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Once you locate the patient record

complete a Follow-up Questionnaire

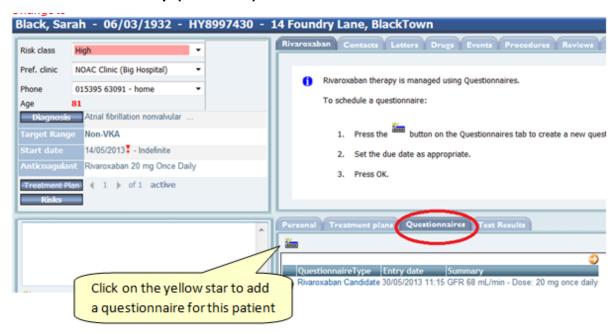
AND

add another Follow-up questionnaire scheduled for the next review date.

(back to Complete a Follow-up page)

(back to Detailed Workflow page)

6.3.1 Schedule a Follow-up (Non-VKA)



On adding an Follow-up Questionnaire, change the 'Due Date' to the date you will complete the details.



Click OK at the bottom of the Questionnaire screen to save this Initiation with the scheduled date.



You will find the questionnaire on the questionnaires tab for later completion.



(back to Complete a Follow-up page)

(back to Detailed Workflow page)

(back to Starting a Non-VKA Treatment Plan page)

6.3.2 Complete a Follow-up (Non-VKA)

The Rivaroxaban **Follow-up Questionnaire** will display details from the patient's treatment plan as shown. It is not possible to schedule a Follow-up Questionnaire unless an active Rivaroxaban treatment plan has been set.



The questions cover

- compliance issues (patient questions and reasons for compliance issues)
- adverse events
- <u>renal function</u> including a calculator for Cockcroft-Gault estimate of CrCl
- records for other tests
- Contraindicated or Interacting drugs including other anticoagulants or platelet inhibitors
- Contraindicated conditions and Haemorrhagic Risks
- records for <u>CHADS2 and HASBLED</u> scores
- notes for planned procedures or other comments

Once you have answered all questions, click on 'Mark as complete' and then <u>schedule another Follow Up</u> for your patient. See <u>details of the Follow-up Questionnaire</u>.



If you cannot answer some questions, simply click OK or Save and come back later to complete the answers.

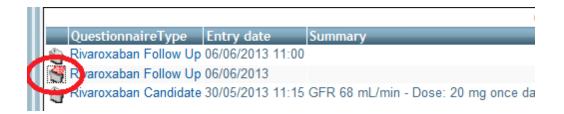
Mark as complete

On marking the answers as complete you are confirming that DAWN can store this record, display a summary on the questionnaires tab and check details against the treatment plan.

If you've added some details in error, Cancel your changes using 'Cancel' or the rewind button at the top of the screen -



If you need to delete a questionnaire completely, look for the bin symbol on the questionnaires tab and save before confirming you wish to delete this record-



If you need to add more information or adjust the Follow-up Questionnaire which is already completed -

- 1. locate the completed questionnaire on the Questionnaires tab
- 2. select Unlock to edit

Unlock to edit

3. save your changes

NB - unlocking a previous questionnaire to edit it may cause the details to be updated with subsequent changes to the patient details. For example, if the patient was previously on an interacting drug which was later removed from your DAWN database, the drug would still be stored in the old completed questionnaire. On unlocking the old questionnaire, the record for this drug may no longer be available.

(back to Detailed Workflow page)

6.3.2.1 Patient questions

It may be useful to record patient feedback on the following questions in the 'Rivaroxaban Follow Up Questionnaire'

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(back to Complete a Follow-up page)

6.3.2.2 Reasons for compliance problems

Please tick any of the compliance problems which apply to your patient. These problems may be important in dosing decisions for Rivaroxaban.

Reasons for compliance problems:	Dementia
	Fear of side-effects
	Gastrointestinal Bleed
	Lack of information
	Lives alone
	Multiple medications
	Prescriptions from several doctors

The list of compliance problems may be edited / added to by your system administrator using the General Look Up Category Table called 'ComplianceReason'.

(back to Complete a Follow-up page)

6.3.2.3 Adverse events reported

Please tick any of the adverse events which apply to your patient. These events are identified in prescribing guidelines as significant events for consideration in dosing decisions for Rivaroxaban.

Has the patient reported any adverse event (potentially due to current anticoagulant)?:	☐ Anaemia ☐ Bruising ☐ Change in colour of stools
	☐ Epistaxis ☐ Haematoma ☐ Vomiting blood

The list of adverse events may be edited / added to by your system administrator using the General Look

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Up Category Table called 'Adverse Bleed Events'.

NB - any events identified on the Follow-up Questionnaire will **NOT** automatically display on the Events tab of your patient screen.

Please click on 'Events' tab to fully record events on the patient screen.

(back to Complete a Follow-up page)

6.3.2.4 Renal function

Estimates of renal function may be recorded in several ways on the Follow Up Questionnaire and these will be used to modify the suggested dose where renal function is severely impaired or not recorded.

- measured creatinine clearance (laboratory estimation)
- Estimated Glomerular Filtration Rate (eGFR)
- serum creatinine
- Cockcroft-Gault estimation of creatinine clearance
- other measures may be recorded in the notes box

DAWN provides a calculator for estimating renal function from serum creatinine and body weight. Enter these 2 values and click on the 'Calculate Cockcroft-Gault CrCL'.



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Note - if you have a laboratory estimation which is less than a numeric value (like <30), please enter the number (like 30) in the Measured Creatinine Clearance or Serum Creatinine boxes. Similarly for results which are reported as greater than a value (like > 220), please enter the numeric value (like 220).

The limits used for renal impairment are set as follows in DAWN -

- Severe renal failure is defined as measured creatinine clearance or estimated glomerular filtration rate or Cockcroft-Gault estimation of CrCl less than 15mL/min.
- If more than one measure of renal function is entered, measured creatinine clearance is considered in preference to estimated glomerular function rate in preference to Cockcroft-Gault estimation of creatinine clearance
- Moderate to severe renal impairment is defined as measured creatinine clearance = 15-50 L/min or estimated glomerular filtration rate = 15-60 mL/min or Cockcroft-Gault estimation of CrCl = 15-

Note – 15-50 is taken to mean greater than equal to 15 and less than 50.

(back to Complete a Follow-up page)

6.3.2.5 Contraindicated drugs

Some concomitant drugs may be known to be contraindicated for the chosen anticoagulant as published in the prescribing guidelines. Please tick any drugs if your patient is currently prescribed this drug.

OTHER ANTICOAGULANT (HEPARIN, DABIGATRAN,)
DRONEDARONE
☐ ITRACONAZOLE
KETOCONAZOLE
POSACONAZOLE
RITONAVIR
SINTHROME
WARFARIN

The list of drugs displayed are defined in the Look Up Tables on your DAWN database and additional drugs may be added to this list as required. Please contact your system administrator to add new drug settings to the 'Interacting Drugs' table.

(back to Complete a Follow-up page)

6.3.2.6 Interacting drugs

Some interacting drugs may be known to be increase the haemorrhagic risk if used along with the chosen anticoagulant. See relevant published prescribing guidelines. Please tick any drugs if your patient is currently prescribed this drug.

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ASPIRIN
CLARITHROMYCIN
OTHER NSAIDs
TELITHROMICIN
VORICONAZOLE

The list of drugs displayed and the advice displayed on screen are defined in the Look Up Tables on your DAWN AC database. Updates to the advice or additional drugs may be added to this list as required. Please contact your system administrator to add new drug settings to the 'Interacting Drugs' table.

(back to Complete a Follow-up page)

6.3.2.7 Other anticoagulant or platelet inhibitor

It is important to record any other anticoagulant or platelet inhibitor prescribed along with Rivaroxaban even if this for a short period.



The list of drugs displayed may be added to or edited in the General Lookup Category for 'Anticoagulant or Platelet Inhibitors' - please contact your system administrator to arrange changes to the displayed options.

(back to Complete a Follow-up page)

6.3.2.8 Other contraindications

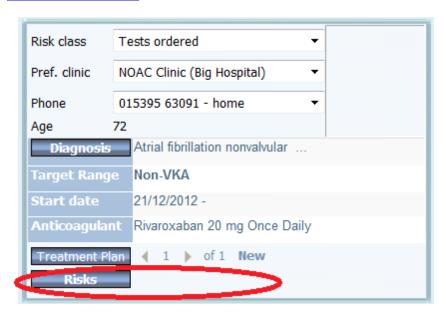
Please tick any of the other contraindications which apply to your patient. These risks are identified in prescribing guidelines as contraindications for dosing with Rivaroxaban.

Other contraindications*:	_
Other contraindications".	Clinically significant active bleeding
	Creatinine clearance <15ml/min
	Hepatic impairment or liver disease expected to have any impact on survival
	Hypersensitivity to tablet excipients or galactise intolerance
	Paediatric Patient
	Pregnancy and breastfeeding
	Prosthetic Heart Valve

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The list of contraindications displayed on the Follow-up Questionnaire may be edited / added to by your system administrator using the Look Up Tables called Risks and Specific Risks.

NB - any risks identified on the Initiation Questionnaire will **NOT** automatically display at the top-left of your patient screen. You may wish to highlight these manually on the patient screen either by <u>adding</u> Risks for a new patient or clicking on the 'Risks' button to add risks for an existing patient screen.



(back to Complete a Follow-up page)

6.3.2.9 Haemorrhagic risks

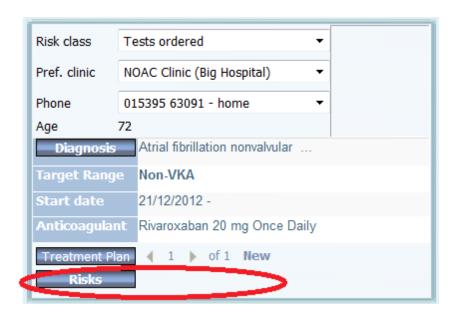
Please tick any of the risks which apply to your patient. These risks are identified in prescribing guidelines as significant risks for consideration in dosing decisions for Rivaroxaban.

Haamarrhagia Dioko*	_
Haemorrhagic Risks*	Active ulcerative gastrointestinal disease
	Bronchiectasis or history of pulmonary bleeding.
	bronchiectasis of history of pulmonary bleeding.
	Congenital or acquired coagulation disorder
	Intraspinal or intracerebral vascular abnormalities
	Recent brain, spinal or ophthalmological surgery
	Recent intracranial or intracerebral haemorrhage
	Uncontrolled severe arterial hypertension
	Vascular retinopathy

The list of haemorrhagic risks may be edited / added to by your system administrator using the Look Up Tables called Risks and Specific Risks.

NB - any risks identified on the Follow-up Questionnaire will **NOT** automatically display at the top-left of your patient screen - see <u>adding Risks for a new patient</u> or click on 'Risks' button to add risks on the patient screen.

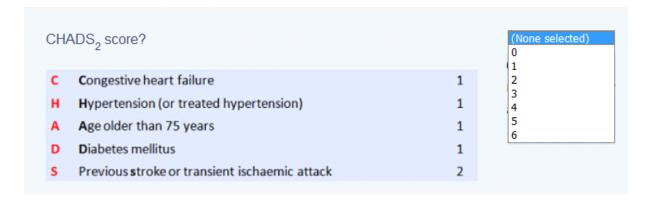
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(back to Complete a Follow-up page)

6.3.2.10 CHADS and HASBLED scores

CHADS2 and HASBLED scores may be optionally recorded form the dropdown menus on your questionnaire.





The dropdown options are provided from the settings in your DAWN Normal Tables, General Lookup

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Category (CHADS2 Score and HASBLED). You may wish to request that your system manager updates the options available.

(back to Complete a Follow-up page)

(back to Settings for General Lookup Category page)

6.4 FAQ - non-VKA records on DAWN

Q Problems activating a treatment plan

A Check the following -

Is the patient is marked 'Active' on the Personal tab?	You may need to click on 'Activate' or Re-activate'
2. Is an Initiation Questionnaire is showing with a dose on the Questionnaires tab?	You may need to complete a questionnaire which is still marked as 'Scheduled'
3. Has the Initiation Questionnaire has different details?	Check that the same diagnosis and dose have been chosen in both the treatment plan and Initiation Questionnaire
4. Is the Initiation Questionnaire marked as 'contraindicated'?	Check that the therapy is suitable for the age / diagnosis / other medications - if it is your DAWN settings may need to be updated by your system manager - contact support@4s-DAWN.com for assistance

Q Why is my patient not on the non-VKA list view?

A Check the following -

1. Has the patient got a DAWN treatment	See adding a new treatment plan
plan for the non-VKA agent?	
2. Have you chosen a date or clinic filter on	Adjust the filters on the left of the list view to see all
the left of the non-VKA list view which	patients with a non-VKA treatment plan
excludes this patient?	

Q Why do I get 'Contraindicated' warnings?

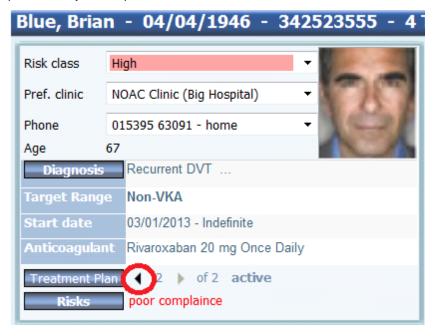
A Contraindications may be for inappropriate concurrent medications (see <u>interacting drugs</u>) or risks (see <u>haemorrhagic risks</u>) or <u>age / renal function</u>.

Q The Rivaroxaban dose I need to use isn't available on the DAWN screen?

A Your DAWN settings may need to be updated by your system manager - contact support@4s-DAWN.com for assistance

Q Where is the INR -warfarin history for my patient now?

A View previous treatment plans using the black arrow on the patient screen and you'll see the History panel for any VKA episode of treatment.



(back to Detailed Workflow page)

Part VIII

7 Changing Anticoagulant

You may wish to record changes in your patient's anticoagulation on DAWN when

Changing between different VKA's (like Warfarin and phenindione)

Changing type of non-VKA (like Rivaroxaban)

Changing between VKA and non-VKA (like Warfarin to Rivaroxaban or vice versa)

Bridging VKA patients with LMWH

(back to Detailed Workflow page)

7.1 Changing between different VKA's

In DAWN, <u>stop the treatment plan</u> and <u>start a new treatment plan</u> for a change in the patient's anticoagulant.



Note - DAWN will prevent a change of anticoagulant within an active treatment plan.

(back to Changing Anticoagulant page)

7.2 Changing type of non-VKA

It is strongly recommended that you <u>stop the treatment plan</u> and <u>start a new treatment plan</u> for any significant change in the patient's anticoagulation.



(back to Changing Anticoagulant page)

7.3 Changing between VKA and non-VKA

In DAWN, <u>stop the treatment plan</u> and <u>start a new treatment plan</u> for a change in the patient's anticoagulant.



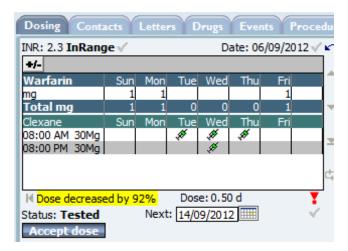
Note - DAWN will prevent a change of anticoagulant within an active treatment plan.

(back to Changing Anticoagulant page)

7.4 Bridging VKA Anticoagulation with LMWH

For customers who use the DAWN Anticoagulation system, LMWH (heparin) doses may be in DAWN within a VKA treatment plan using customised dosing options.

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Please see section on 'Setting up LMWH and Pentasaccharide Agents'

(back to Changing Anticoagulant page)

Part Collins

8 Using the system

DAWN is a web-based software package installed within your network. You should be able to access the system using Internet Explorer from any PC on your site and your local system administrator will set a password for you.

- See how to log in (log in with active directory)
- How to navigate around DAWN
- How to get started
- see an overview of the workflows in DAWN

8.1 Logging Into DAWN

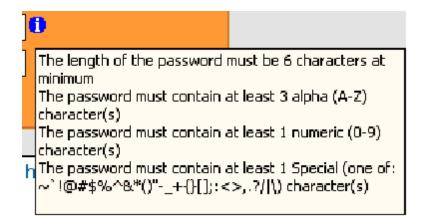
When opening up DAWN, you will need to log in with your user account.

Take care to type your user name and password correctly using the correct combination of capital and small letters, ensuring that the Caps Lock is on and off at the correct times. Take care not to confuse the letter O and the number zero or the letter I and the number one:



If you would like to change your existing password, a new password can be created from this screen. Before doing this, hover your cursor over the blue 'I' icon to the right of the new password field. This gives the criteria that the password must meet:

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Although these settings can be altered within the system, the default requirements are as follows:

- The length of the password must be at least 6 characters long
- The password must contain at least 3 alpha characters, eg, A, B, C, a, b, c etc
- The password must contain at least 1 numeric character, eg, 1, 2, 3, etc
- The password must contain at least 1 special character, eg, *, ", \$, %, etc

For example, a password such as Tracy1! would meet these criteria.

Enter your new chosen password into the New Password and Confirm boxes, before clicking on the Login button:



If your password change has been successful, the system should log you into DAWN.

If you are unsuccessful, a message should appear telling you why, ie, 'user name incorrect', 'password incorrect'.

You are allowed up to three attempts at logging into DAWN before a screen appears saying 'Login Denied! Please contact your system administrator'. If this occurs, you can close down all internet screens and try bringing up DAWN again to log in.

If you then unsuccessfully try to log into DAWN another two times (which totals 5 attempts altogether), then your user account will become locked and another user will need to log into DAWN to unlock it.

If all users are unable to log into the DAWN system, there may be an issue with the DAWN system itself. Please contact your IT department if this occurs.

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8.2 Logging In - Active Directory Support

DAWN supports Active Directory Login. This means users who have a network login can store this ID in DAWN. When they access the application, if DAWN recognises their network ID, it automatically logs them in without prompting them to type a DAWN specific user ID and password.

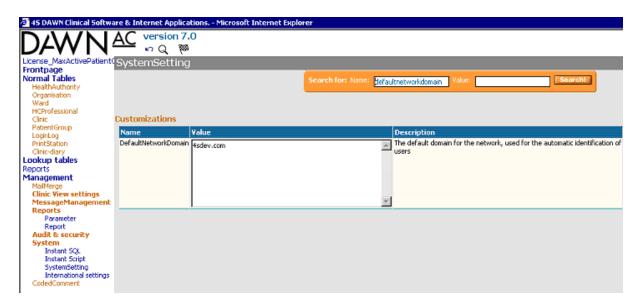
To enable Active Directory Support

To enable Active Directory Support you need to perform the following steps:

- 1. Enable Active Directory support in DAWN
- Update each user's Healthcare Professional Account record with their Network ID.
- Disable anonymous access to the DAWN web site in Internet Information Services to ensure that
 users connect to the web server with their network ID and not with the default Internet Guest
 Account.

Enabling Active Directory Support in DAWN

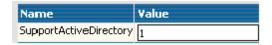
- 1. Press F5 to display the System Menu then choose Management/System to display the system options.
- 2. Click on *SystemSetting*, type "Domain" into the *Search for Name* field and click the Search button. The *DefaultNetwork Domain* system setting is displayed.
- 3. Enter the name of your active directory domain in the Value field.



4. Enter "ActiveDirectory" in the *Search for Name* field and press the Search Button. The *SupportActiveDirectory* system setting is displayed.

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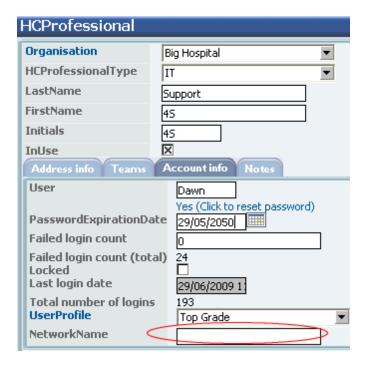
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5. Change the Value to 1 (to disable Active Directory support change the Value to 0).

Updating the Healthcare Professionals' Account Records

- 1. Choose Normal Tables/HCProfessional from the System Menu to display the list of Healthcare Professionals.
- 2. Choose the Edit form icon to the left of the appropriate Healthcare Professional to display their full details.
- 3. Choose the Account tab and enter the user's Active Directory Network User ID in the *NetworkName* field.

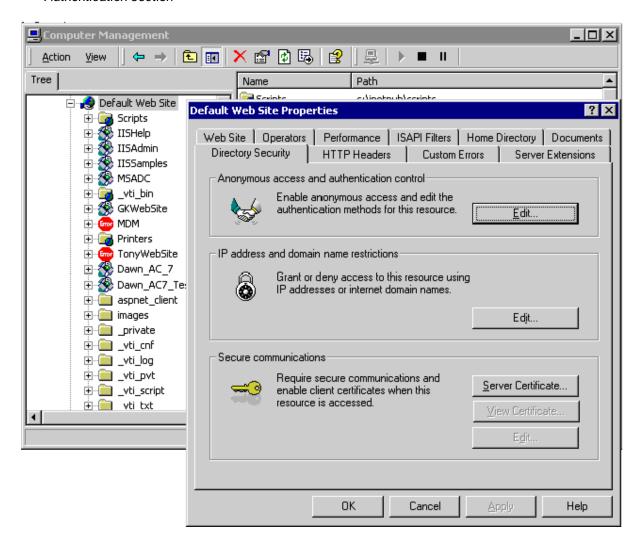


Disabling Anonymous Access to the DAWN website

- 4. Right click on *My Computer* and choose Manage from the pop up context menu to display the Computer Management Console.
- 5. Expand the Services and Applications branch of the menu and click on Internet Information Services.
- 6. Expand the *Web Sites* folder, right click on the Web Site which hosts DAWN and choose Properties from the pop up context menu. The web site properties are displayed.
- 7. Choose the Directory Security page and click the Edit button in the Anonymous Access and

Version 1.0

Authentication section



5. Deselect the *Anonymous Access* option and ensure the *Integrated Windows Authentication* option is selected.

8.3 Workflows in DAWN - an overview

Users – Daily/ Weekly Routines	
Patients for follow-up today	
Select list views for	
Rivaroxaban	
Patients starting on non-VKA	
Use Patient search to select or add the patient to DAWN	
Workflow for a Patient	

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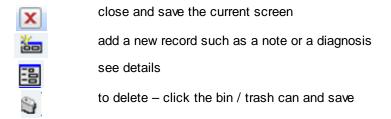
Non-Attendees	
Select list view for Rivaroxaban	
and the filter for Overdue	
Incomplete records	
Select <u>list view</u> for Rivaroxaban	
and the filter for No next review date	
Listings Reports	
Select Reports from the front menu as required	

(back to Detailed Workflow page)

8.4 How To Navigate Around DAWN

HOW TO NAVIGATE AROUND THE DAWN SCREENS

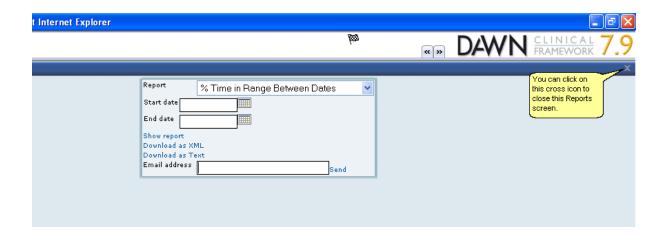
There are several ways of moving through the different screens within DAWN.



To log out of the system, you can use the Flag icon:



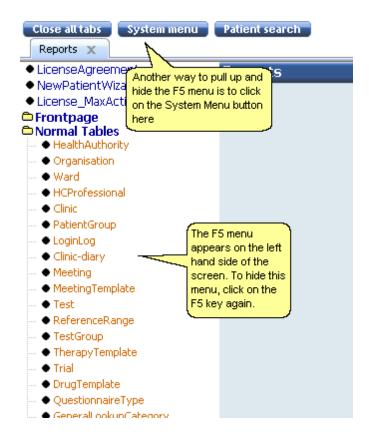
To close individual screens within DAWN, you can use the black cross on that page:



To view a page you have already opened previously, you can choose the screen you require from the tabs list at the left of the screen:



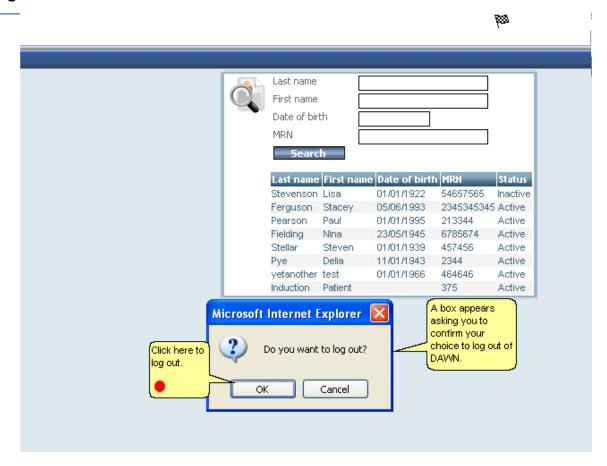
To bring up an additional menu on the DAWN front screen, choose the F5 key on your keyboard, or click on the Sys Menu button at the top left of the screen:



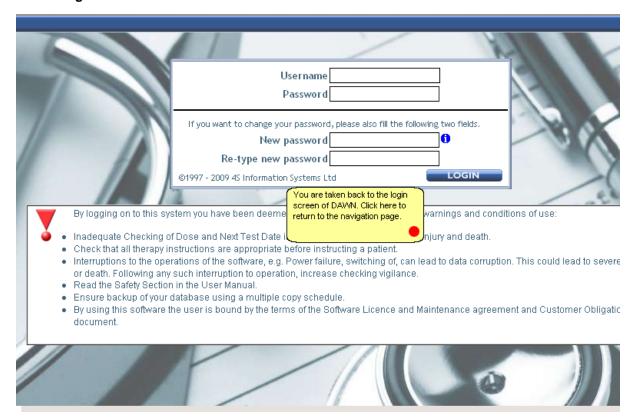
To close all open screens and go back to the original DAWN front screen from anywhere within the system, click on the Close All Tabs button at the top left of the screen.

To search for a patient from anywhere within the system, click on the Search button at the top left of the screen.

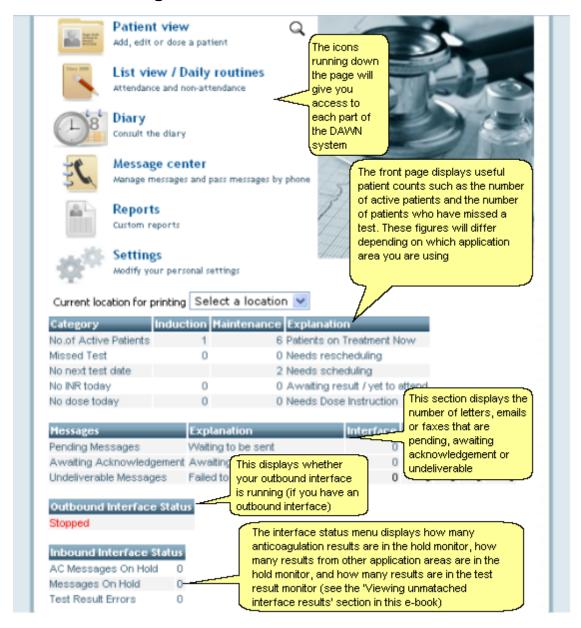
8.4.1 Login Confirmation Screen



8.4.1.1 DAWN Login Screen



8.5 DAWN Front Page



8.6 List Views - What are They?

List Views are lists of patient records selected and ordered on predefined criteria.

Use List Views to quickly access records for

- patients due for review today
- patients with missed reviews
- reminders outstanding, ...

Up to 10 List Views can be configured in your DAWN system.

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The user can apply filters such as date range or patient status to refine the list of records viewed. Bulk messages can be sent for patients identified on a List View.

If you edit/amend list views within the system, remember to check all changes thoroughly. This can be done using a 'dummy' patient within the system.

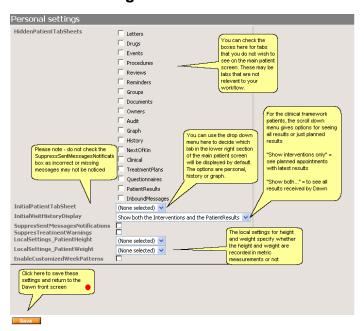
Click **HERE** to learn how to use list views.

8.7 Personal Settings

DAWN Personal settings are user specific and can be used to determine which tabs and screens the user will and will not view within the system.



8.7.1 Personal Settings Form



8.8 Getting Started Workflow



WORKING THROUGH THE SYSTEM

Before starting to dose patients and use the DAWN system in a live situation, we need to set up several sections first. This configures the DAWN system to your specific needs, so that patients can be monitored quickly and effectively, and all the information logged against them is correct, *ie* the patient is booked into the correct clinic at the correct time, and has the correct referring GP and consultant details.

In order to initially start using the system, you can go through some of these steps in order.

Read the Safety Section of the Manual. Read the Customer Obligations Section of the Manual. Add a new Health Authority.
This groups the
Organisations within your
system.

Add a new Organisation. We need to add these so that healthcare professionals and clinics can belong to a specific organisation.

Add a new Organisation Ward.

Add a new Patient Group. You can optionally add patient groups in order to define particular subsets of patients within the system.

Add a new User Profile. We need to add user profiles so that different users can access specific parts of the system.

Add a new Healthcare Professional. We need to add healthcare professionals so that they are logged within the system and can optionally access their patients.

Add a new Clinic. We need to add clinics so that patients cqan be booked into the correct clinic within the system.

Once the above settings are all in place, follow the Workflow for a Non-VKA Patient

8.9 Printing from DAWN

To send a letter to a patient (or colleague), select the patient record and click on the Letters tab at the

top. The following dropdown menus show the letter templates loaded in your system. Contact your system administrator to amend or add new templates.

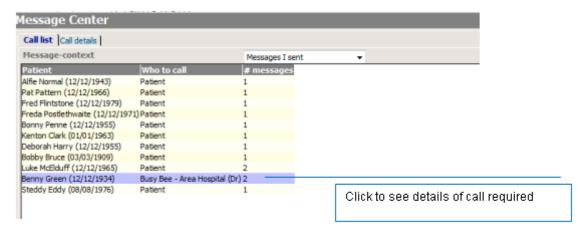
Select a Direct Print (local printer) – uses your local printers (and any network printers you can see) from your PC

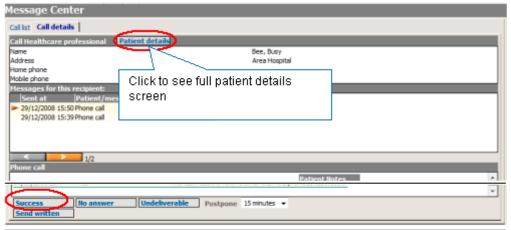
Select a custom message to send – uses available network printers via DAWNMailer and can send messages by fax / e-mail / phone

If you use DAWN Mailer, you can choose a specific location for printing on the front screen. This means that if you are working in the administration office you can ensure your letters print on the administration office printer, whereas if you are in a clinic room you can ensure your letters printer on the clinic room printer. You can generate letters from List Views as well as automatically on scheduling / authorising appointments (via 'Message Events').



8.10 Message Center



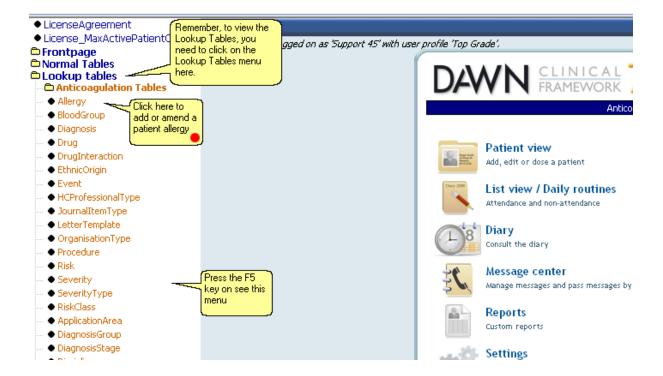


Part

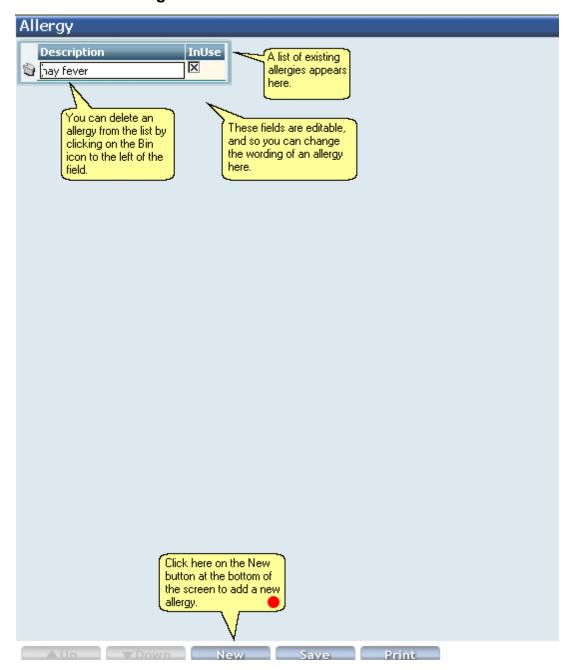
9 Configuring your system

9.1 Adding/Editing Allergies

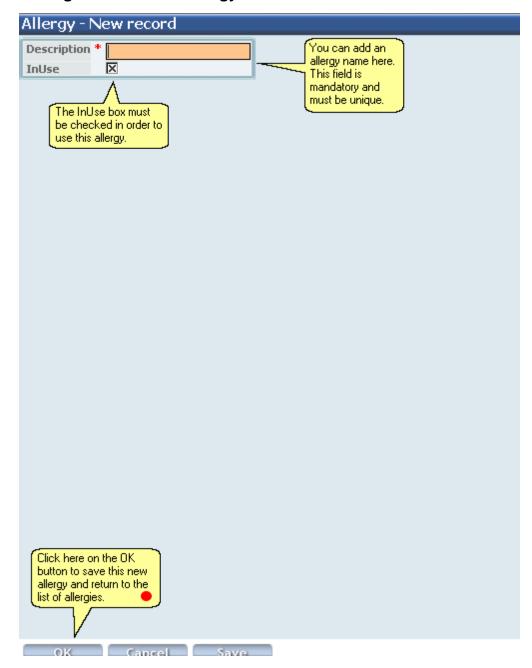
If you need to add an allergy for a patient that does not exist in the standard list, new allergies can be added here.



9.1.1 List of Patient Allergies

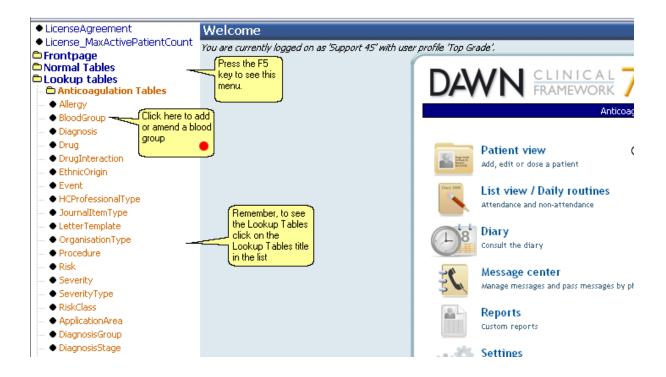


9.1.2 Adding a New Patient Allergy

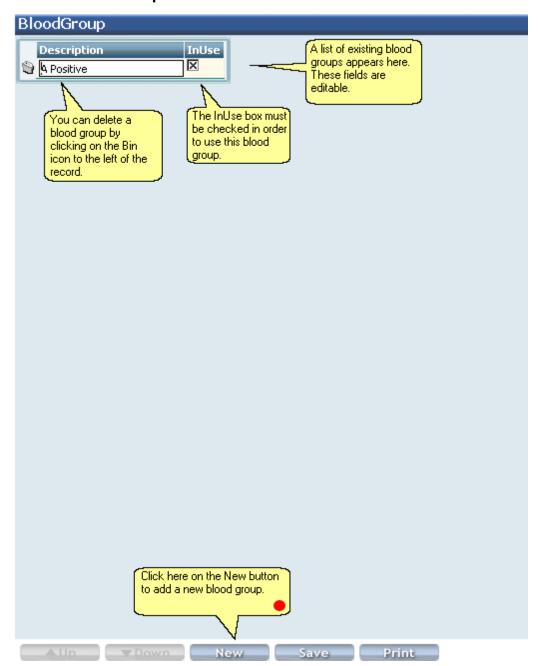


9.2 Adding/Editing Blood Groups

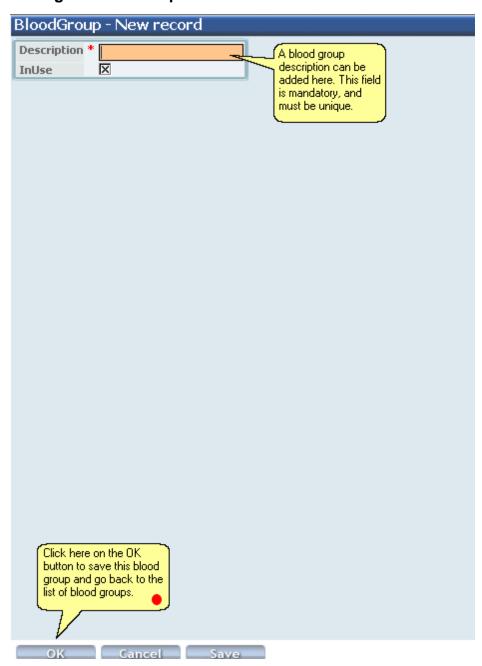
If you need to add an blood group for a patient that does not exist in the standard list, new blood groups can be added here.



9.2.1 List of Blood Groups

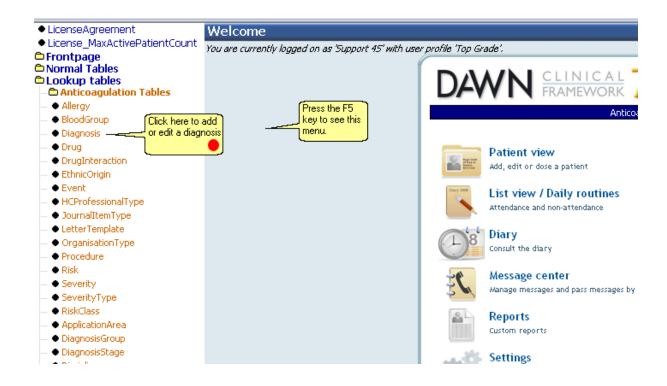


9.2.2 Adding a Blood Group

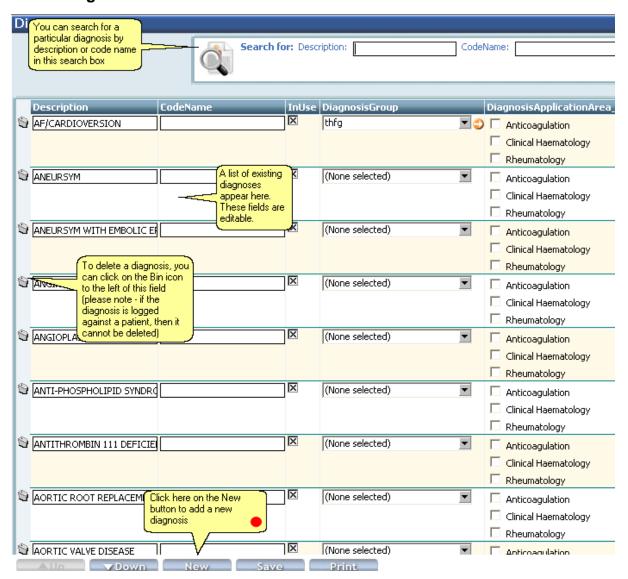


9.3 Adding/Editing Diagnoses

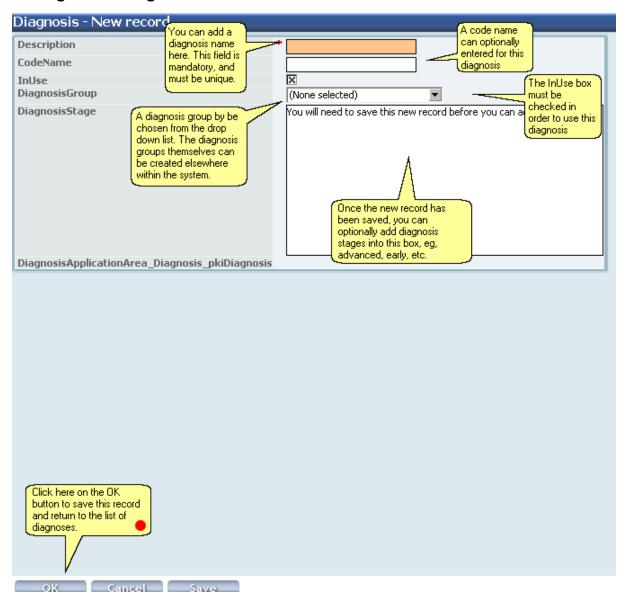
If you need to add a diagnosis for a patient that does not exist in the standard list, new diagnoses can be added here.



9.3.1 List of Diagnoses

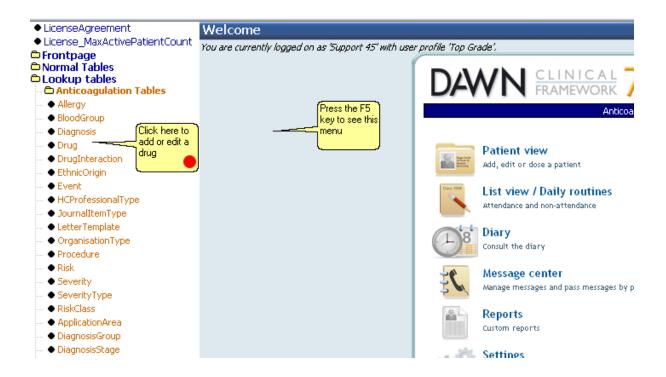


9.3.2 Adding a New Diagnosis

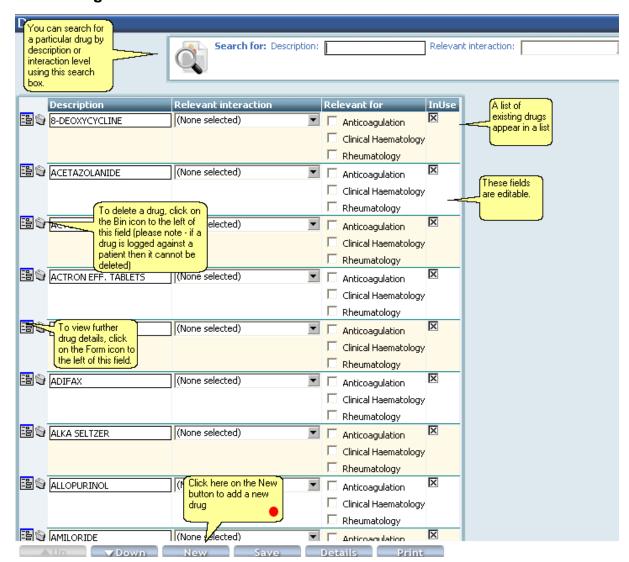


9.4 Adding/Editing Drugs

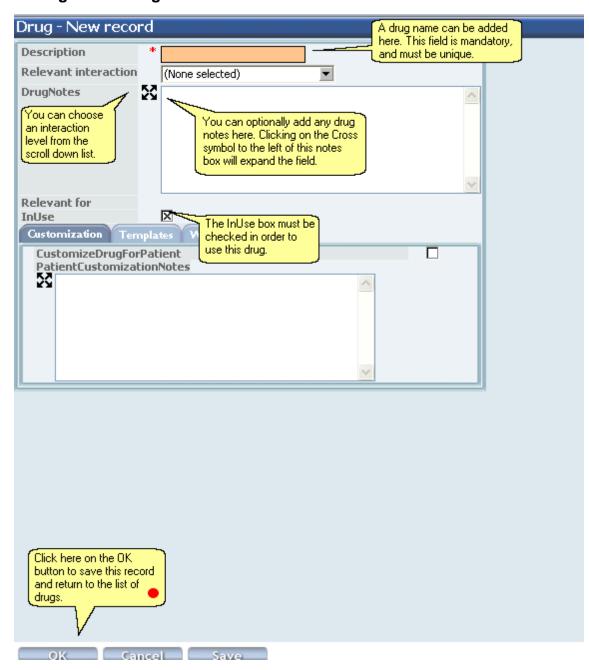
If you need to add a drug for a patient that does not exist in the standard list, new drugs can be added here.



9.4.1 List of Drugs

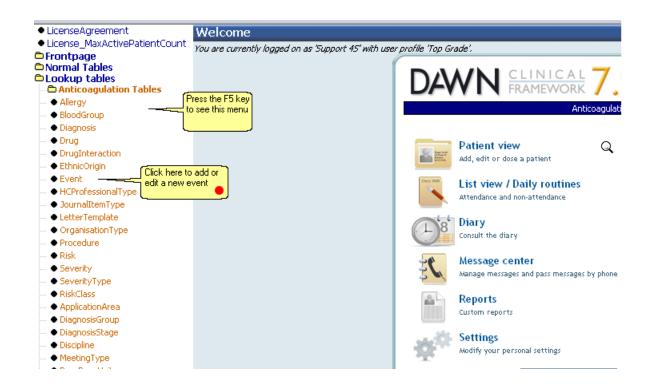


9.4.2 Adding a New Drug

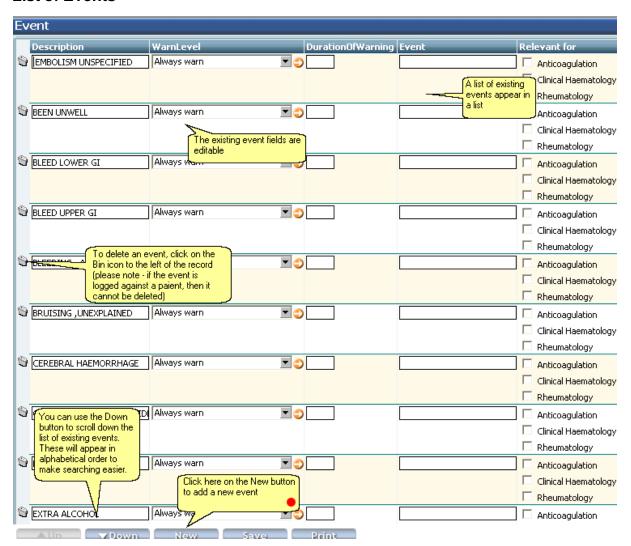


9.5 Adding/Editing Events

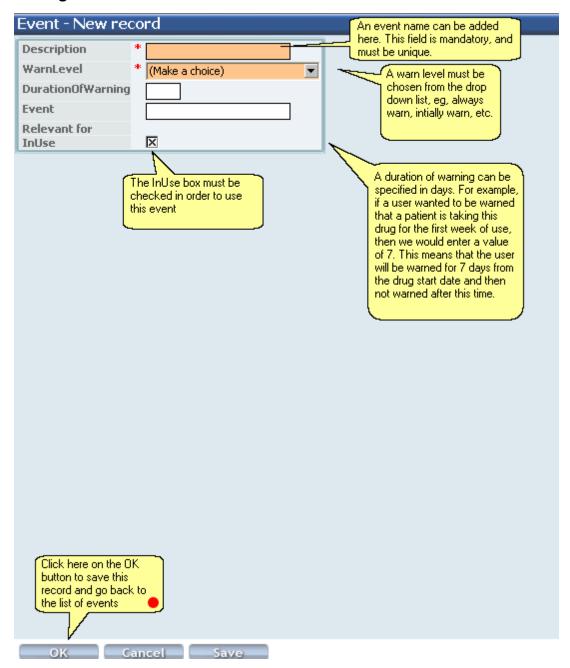
If you need to add an event for a patient that does not exist in the standard list, new events can be added here.



9.5.1 List of Events

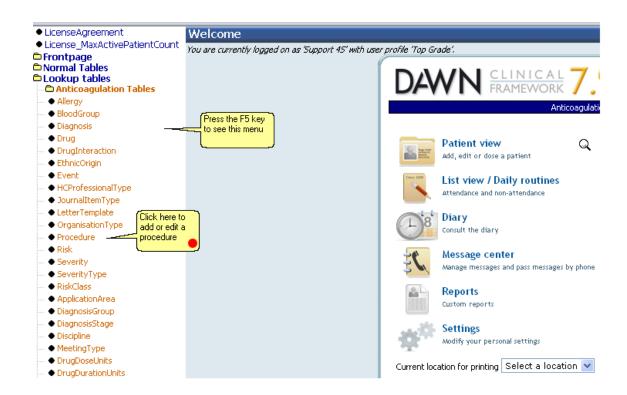


9.5.2 Adding a New Event

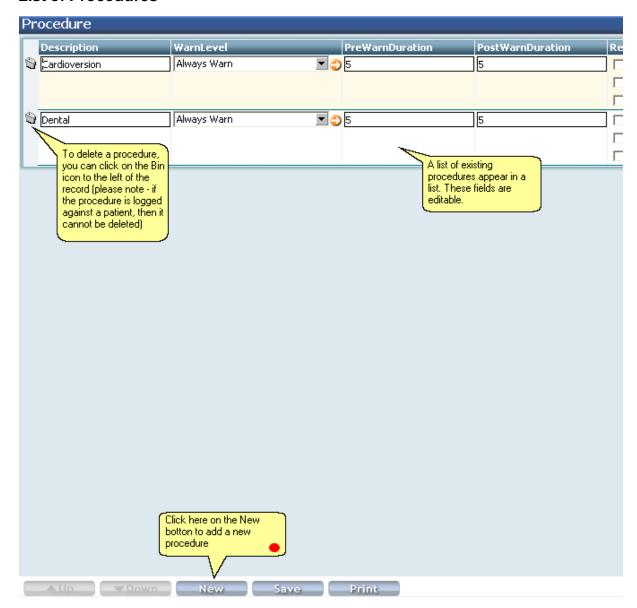


9.6 Adding/Editing Procedures

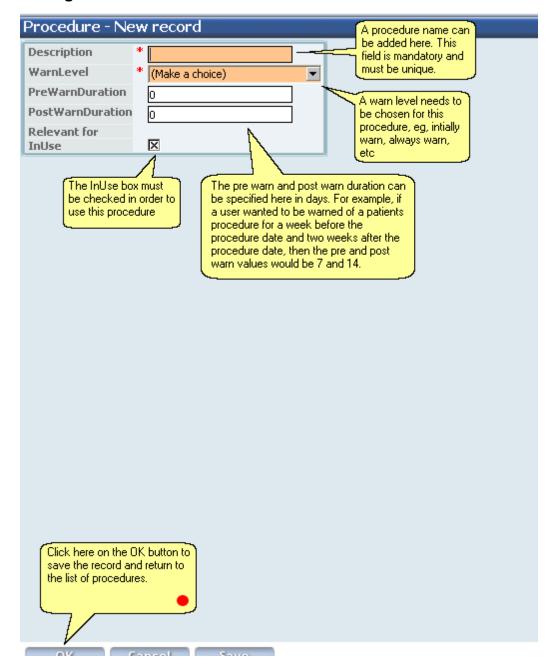
If you need to add a procedure for a patient that does not exist in the standard list, new procedures can be added here.



9.6.1 List of Procedures

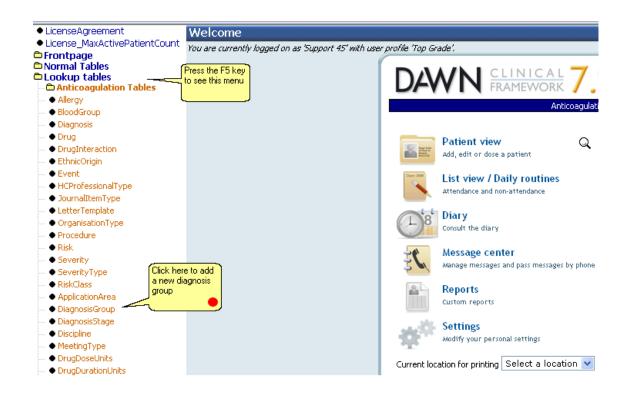


9.6.2 Adding a New Procedure

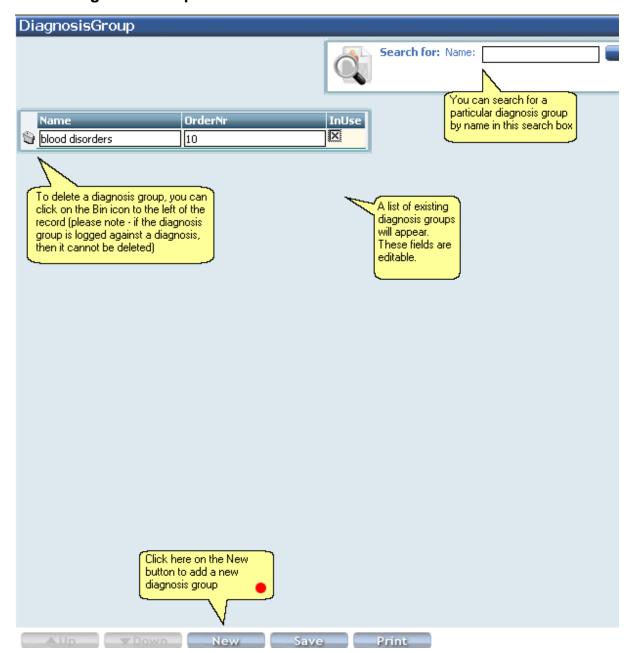


9.7 Adding/Editing Diagnosis Groups

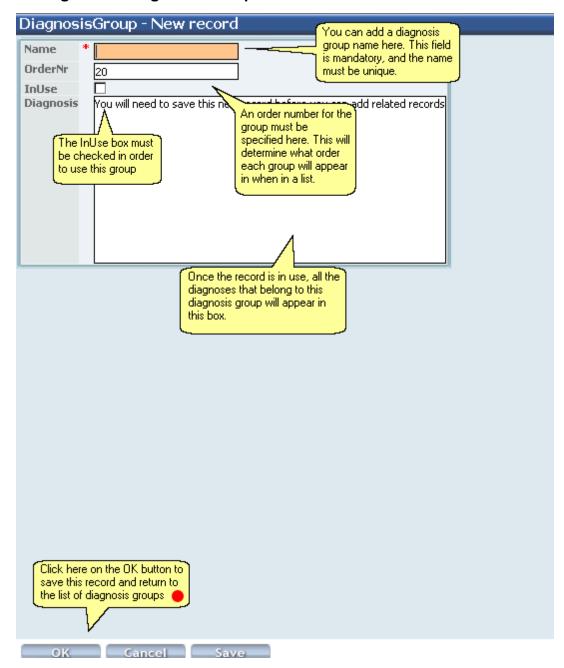
If you need to add a diagnosis group for a diagnosis that does not exist in the standard list, new diagnosis groups can be added here.



9.7.1 List of Diagnosis Groups

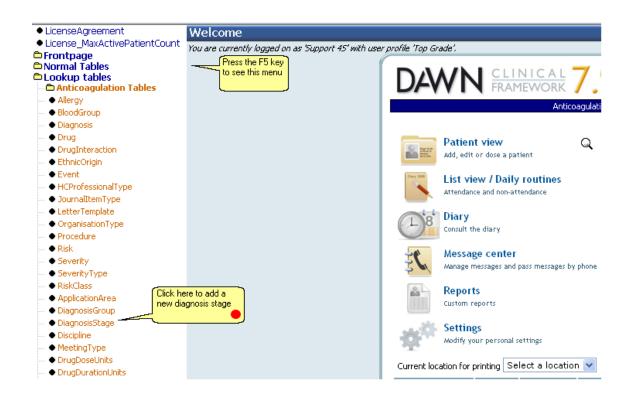


9.7.2 Adding a New Diagnosis Group

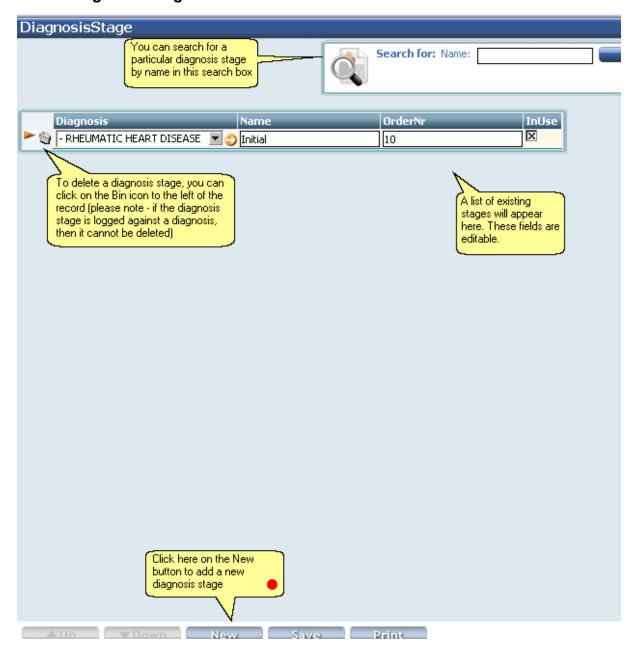


9.8 Adding/Editing Diagnosis Stages

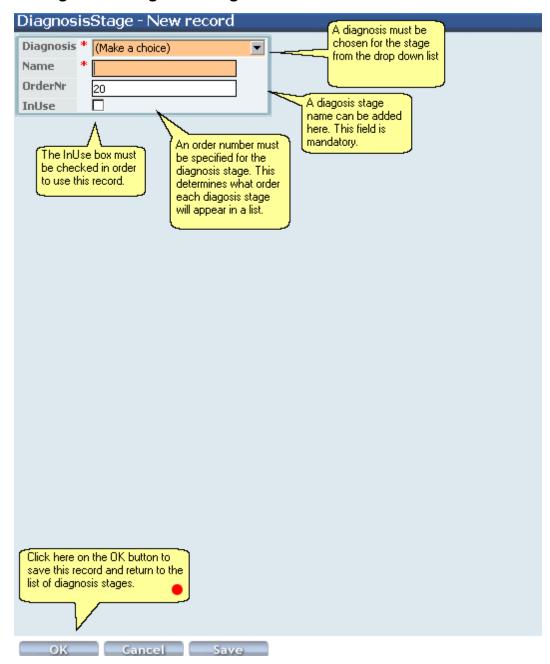
If you need to add a diagnosis stage for a diagnosis that does not exist in the standard list, new diagnosis stages can be added here.



9.8.1 List of Diagnosis Stages

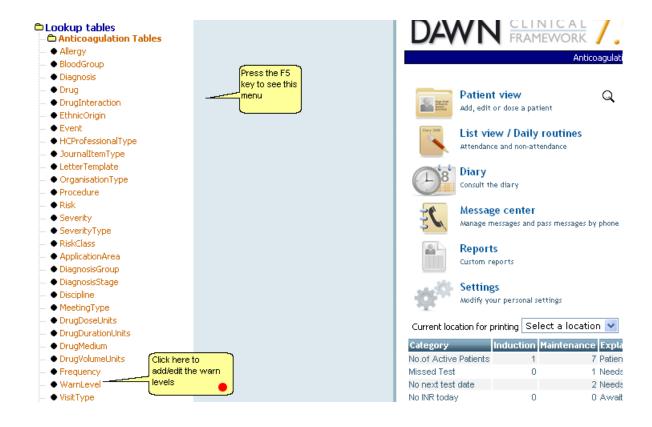


9.8.2 Adding a New Diagnosis Stage

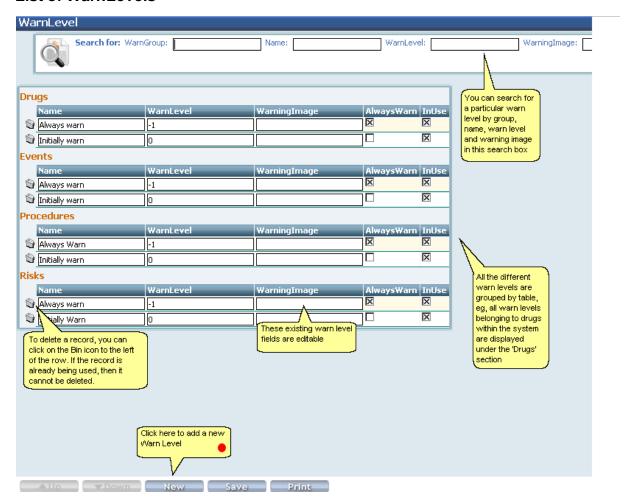


9.9 Adding/Editing WarnLevel

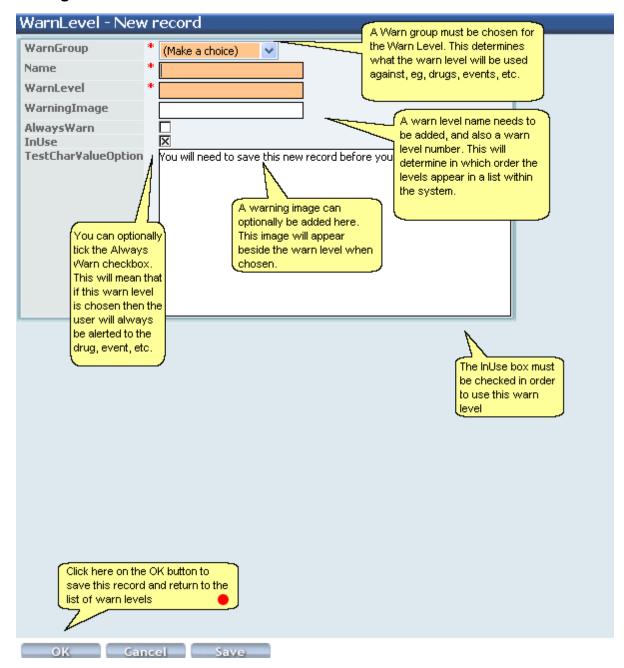
If you need to add warn levels to drugs, events, etc that do not exist in the standard list, new warn levels can be added here.



9.9.1 List of WarnLevels

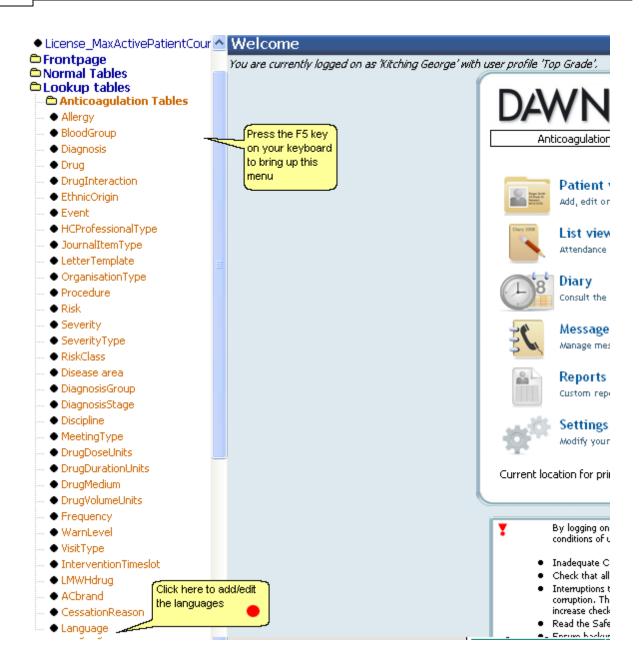


9.9.2 Adding a New WarnLevel

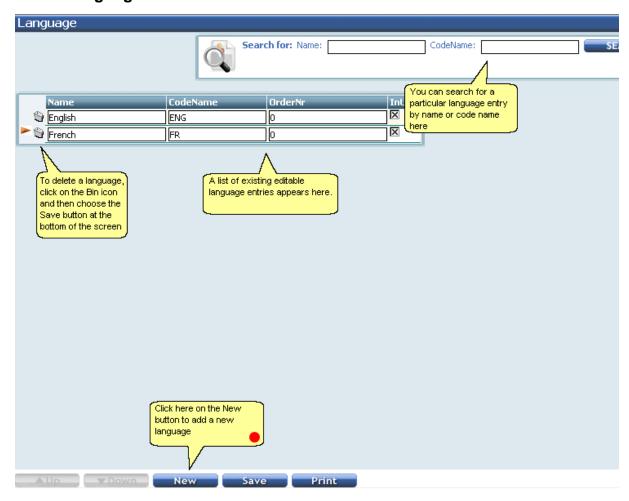


9.10 Adding/Editing Languages

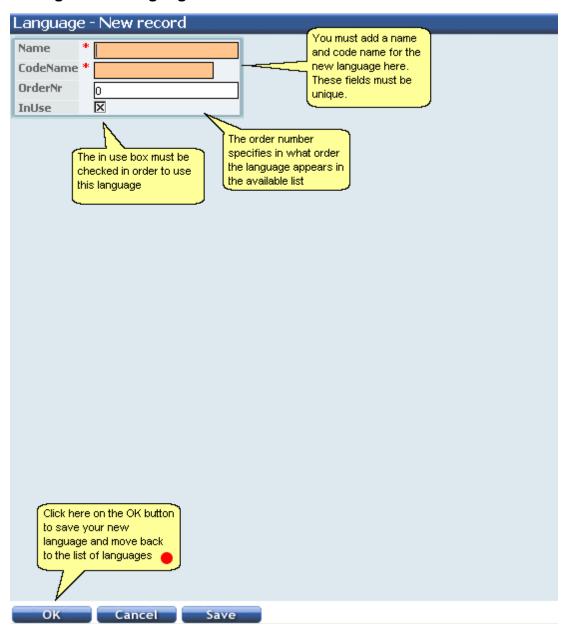
If you need to add a language for a patient that does not exist in the standard list, new languages can be added here.



9.10.1 List of Languages



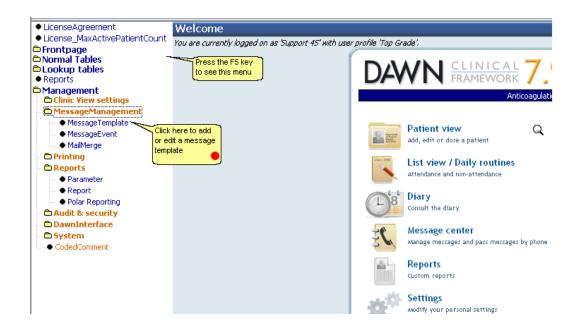
9.10.2 Adding a New Language



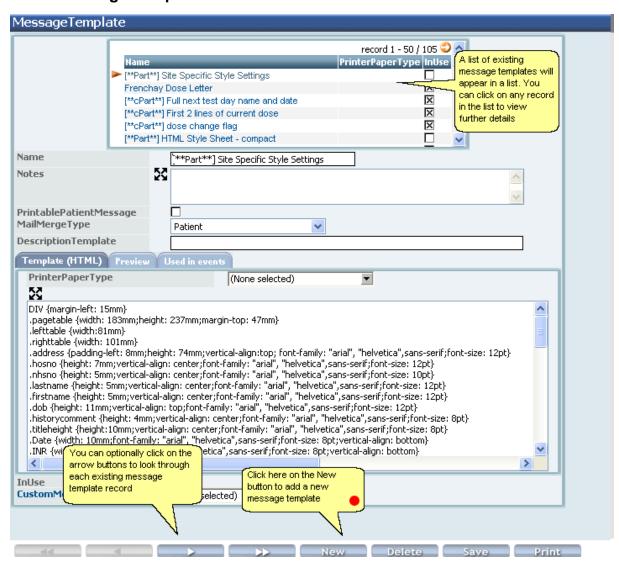
9.11 Adding/Editing a Message Template

Letters and forms can be configured within the DAWN system. These need to be tested thoroughly if edited or added. The support team at DAWN can configure message templates for you if these are needed. Please test any new/amended message templates carefully before using with real patient data.

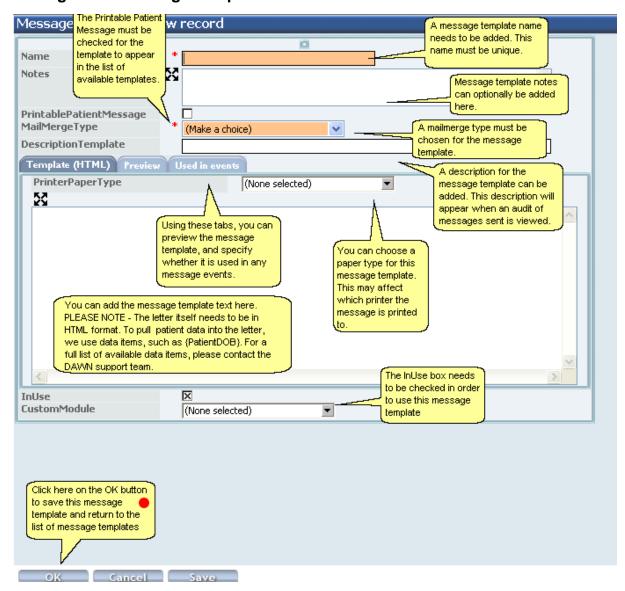
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9.11.1 List of Message Templates



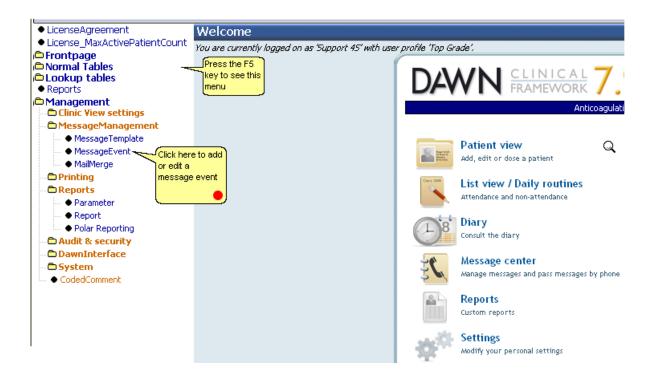
9.11.2 Adding a New Message Template



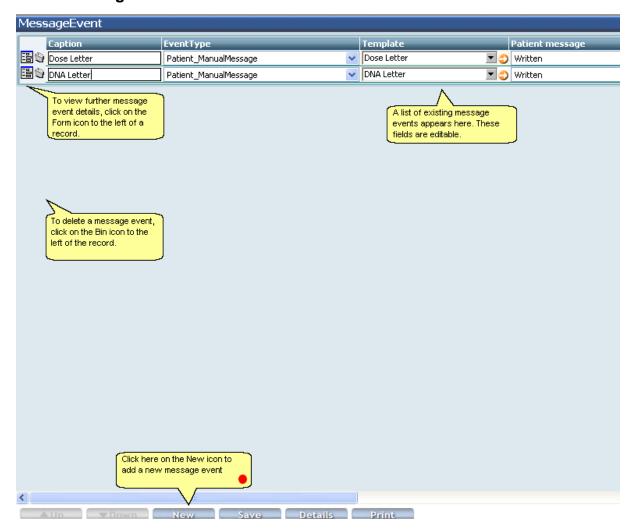
9.12 Adding/Editing a Message Event

Message events can be created so that messages can be automatically printed, faxed, emailed or sent to a phone list when certain actions are carried out within the system. Please test messaging settings carefully before using with real patient data.

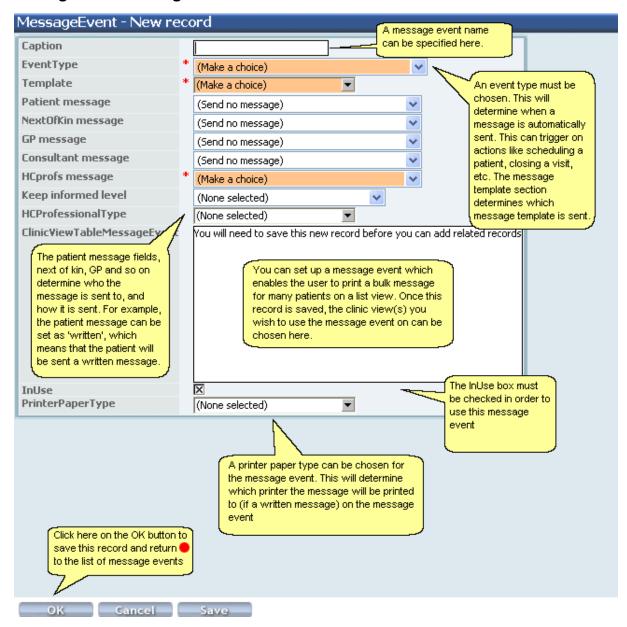
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9.12.1 List of Message Events



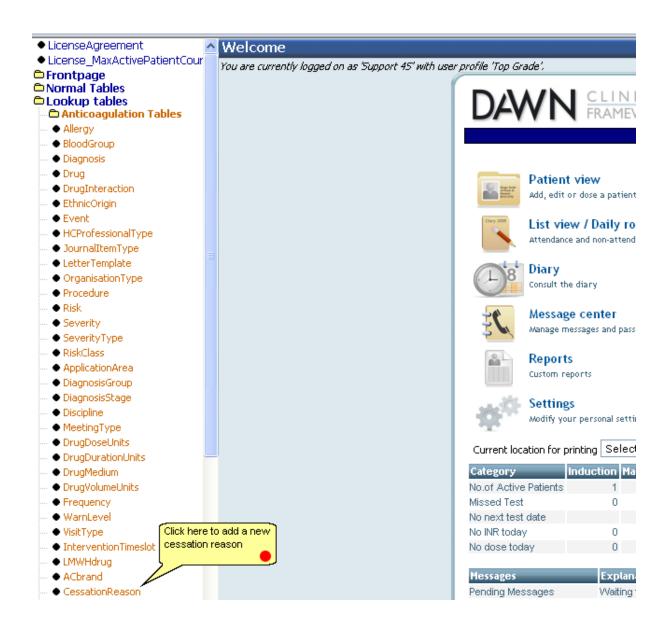
9.12.2 Adding a New Message Event



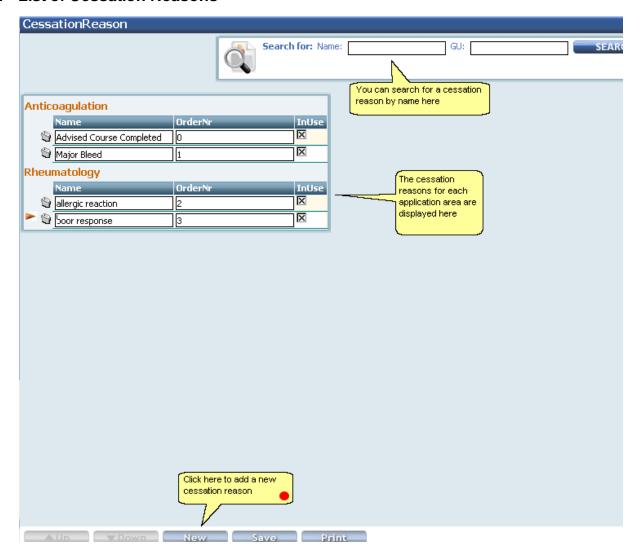
9.13 Setting up a Cessation Reason

Different cessation reasons can be set up within DAWN so that this can chosen within the patient's treatment plan.

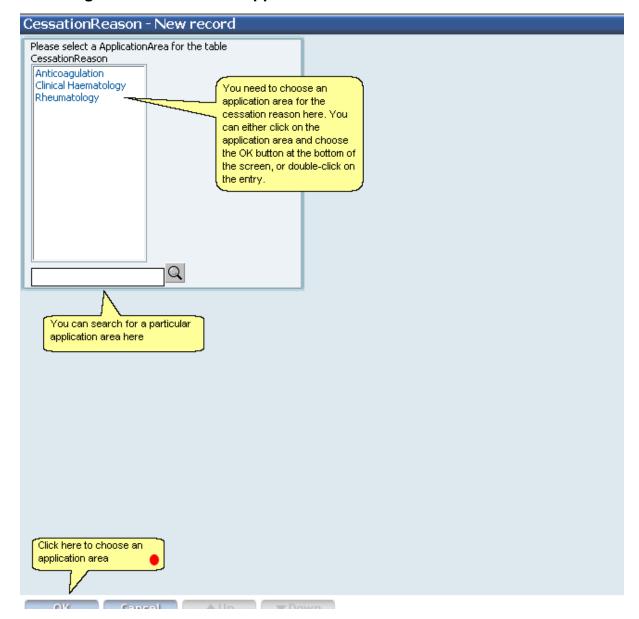
Please note - once a cessation reason has been added into DAWN, the cessation reason will then become a mandatory field to fill in within the patient's treatment plan.



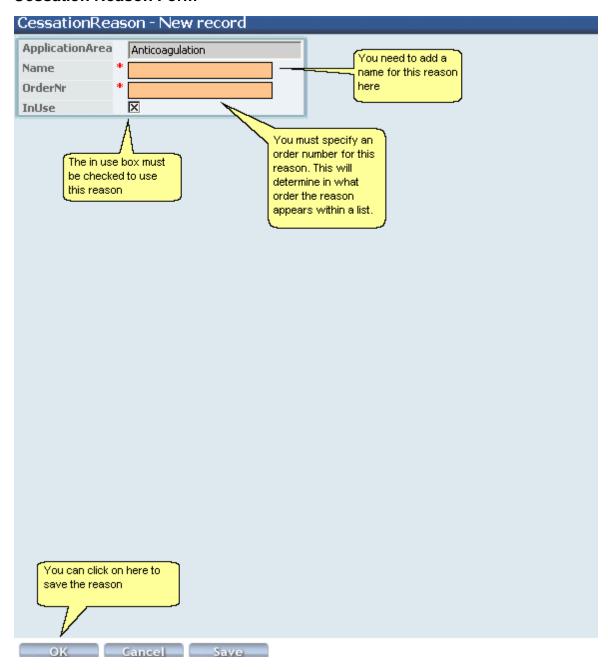
9.13.1 List of Cessation Reasons



9.13.2 Choosing Cessation Reason Application Area



9.13.3 Cessation Reason Form



9.14 Coded Comments

You can define short codes for frequently used comments; for example "nbb" for "no bleeding or bruising".

The *CodedCommentPrefix* system setting is used to define a prefix ("." by default) that identifies the text you type (in any notes field) as a short code.

As such you could type ".nbb" anywhere in a Patient Note, Treatment Note or Quick Note

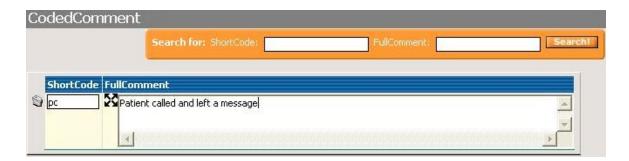
and this would automatically expand to say "no bleeding or bruising" when the note is saved.

To define coded comments:

- Press F5 to display the system menu.
- Choose Management/Coded Comments to show the coded comments list (this is empty to start with):



Choose the New button to add a coded comment:



- Save your comment.
- In your patient notes screen place your code, i.e. ".pc":



• When you SAVE the coded comment, the full comment will appear on the screen:



9.15 Risk Settings

There are 3 steps involved in configuring the Risk and Risk Class:

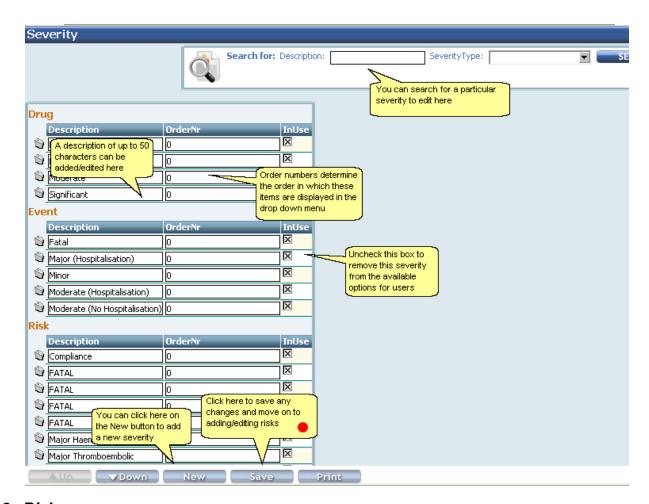
- Set Severity for Risk
- Set Risk
- Set Risk Class



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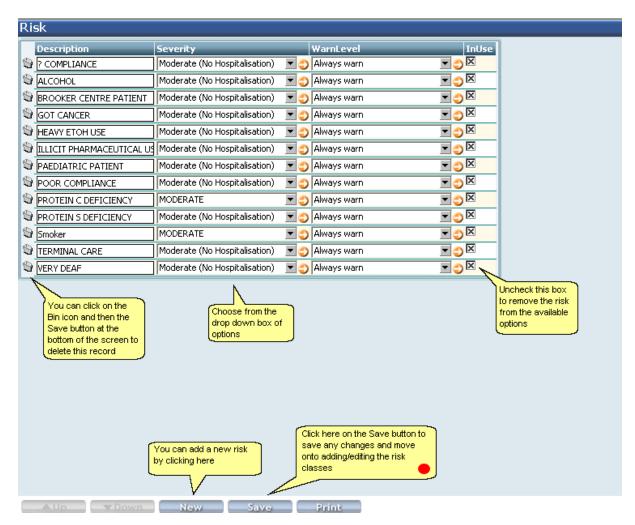
9.15.1 Severity of Risk Setting

From the Lookup tables, set Severity for Risk.



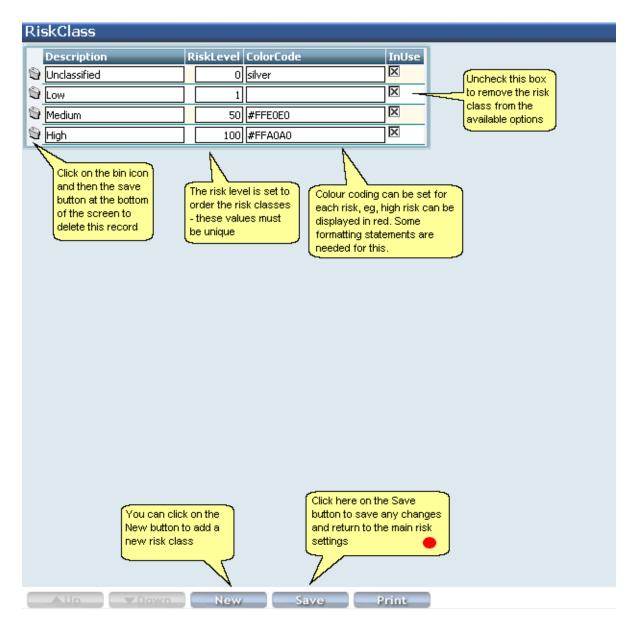
9.15.2 Risk

Add or edit Risk from the Lookup tables on the F5 menu.



9.15.3 Risk Class

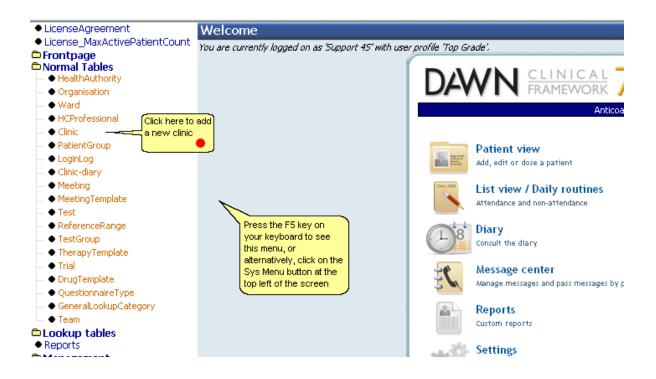
A risk class can be chosen for a patient to indicate what their risk level is, eg, high risk, low risk. This risk class appears on the top left of the main patient screen. Risk Class options can be added / edited from the Lookup Tables on the F5 menu.



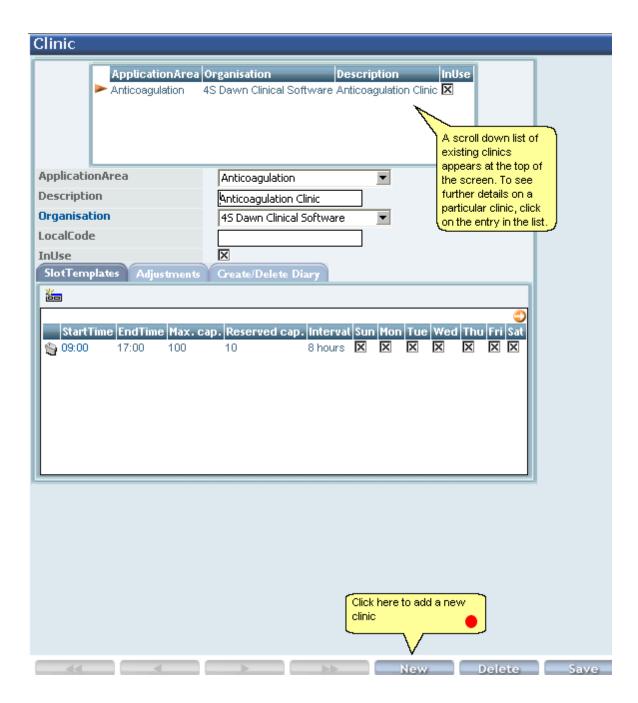
9.16 Adding a New Clinic

Clinics must be set up within the system so that patients can be booked into these clinics for each visit. Patients can also be logged as having a particular preferred clinic. You will need to set up an Organisation before creating a new clinic.

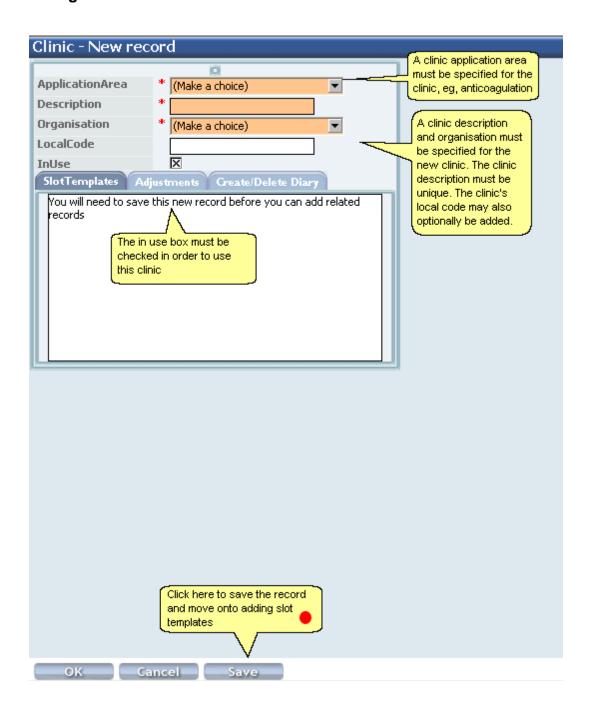
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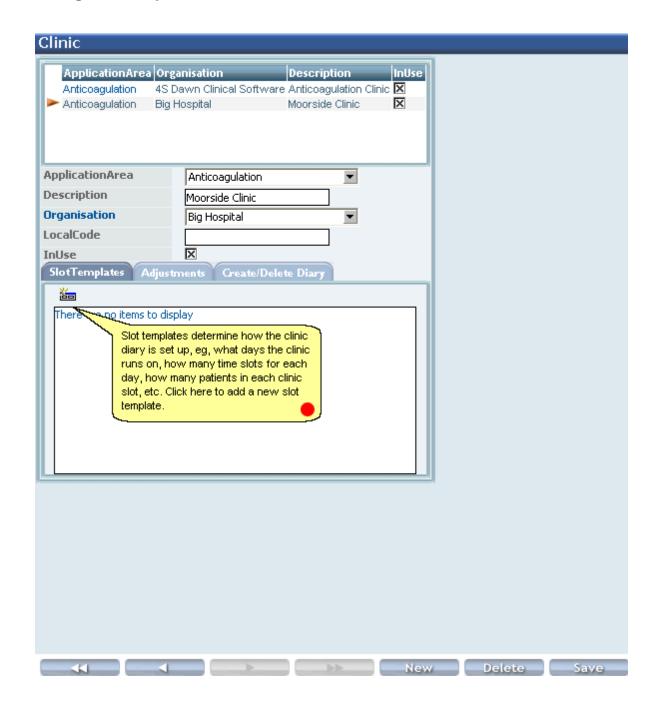
9.16.1 List of Clinics



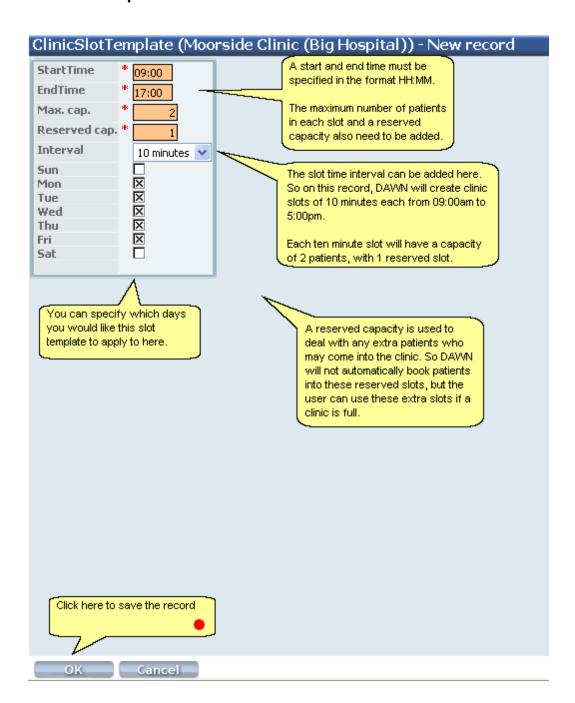
9.16.2 Adding Clinic Details



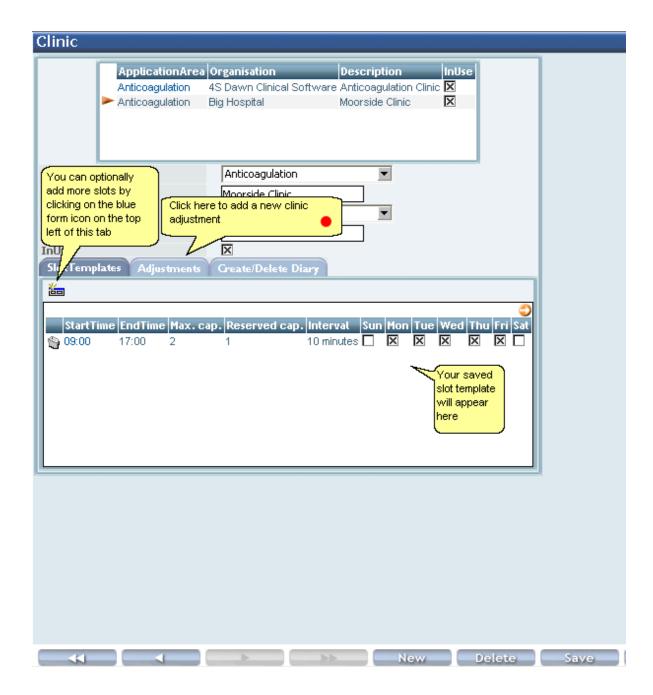
9.16.3 Adding Slot Templates



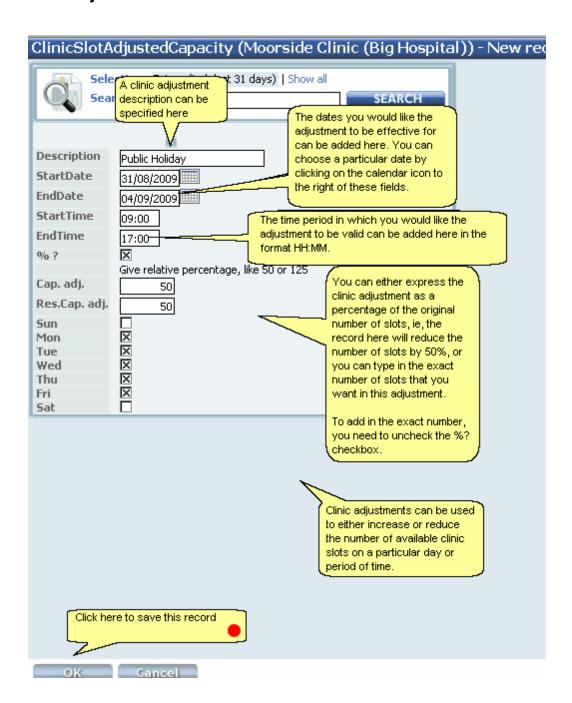
9.16.4 New Slot Template Form



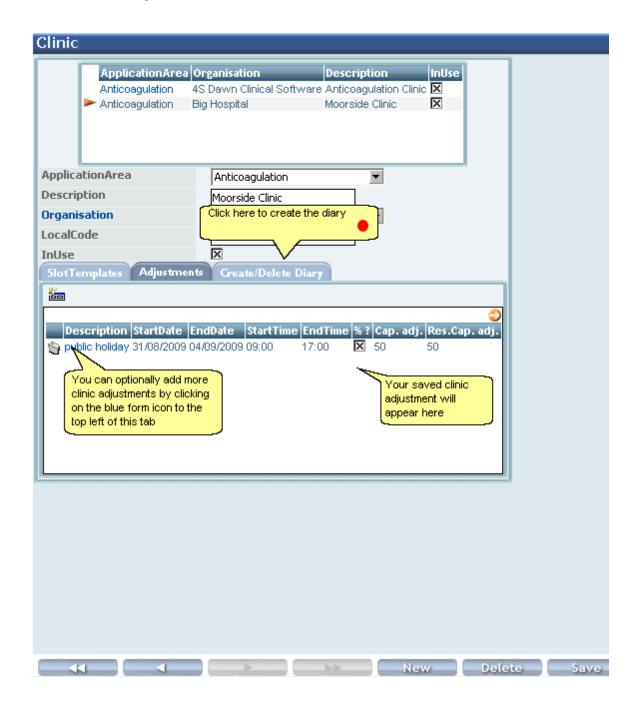
9.16.5 Saved Slot Template Form



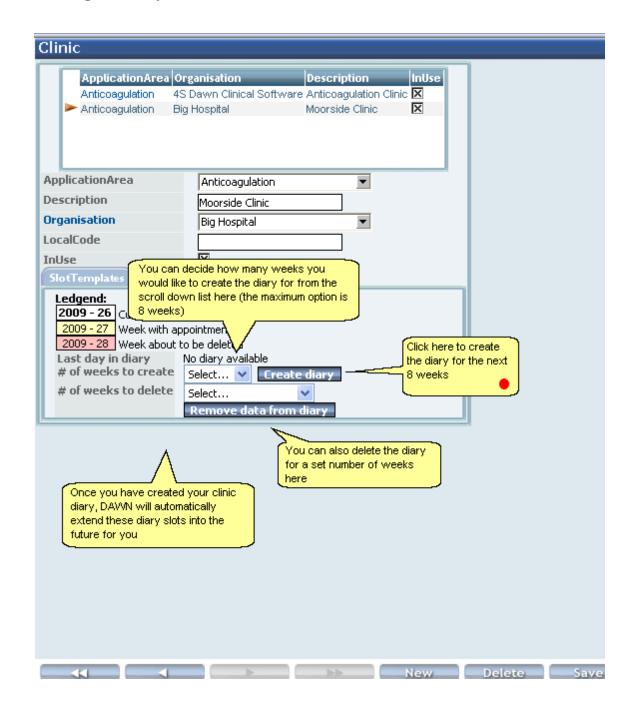
9.16.6 Clinic Adjustment Form



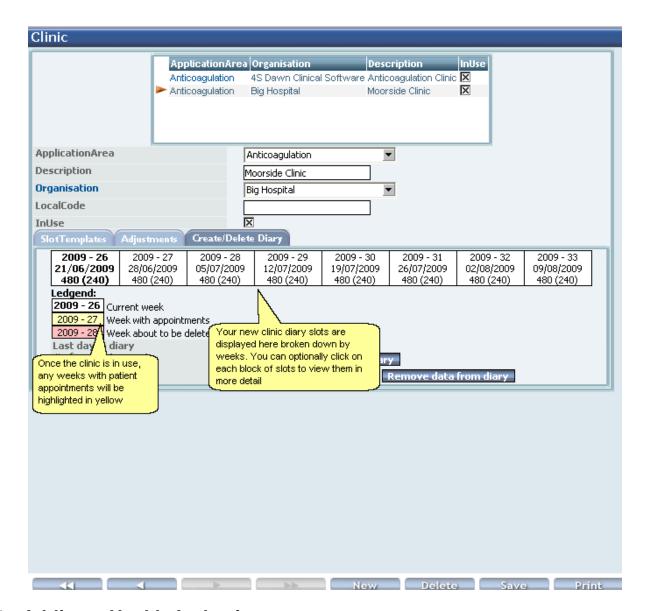
9.16.7 Saved Clinic Adjustment Form



9.16.8 Creating the Diary

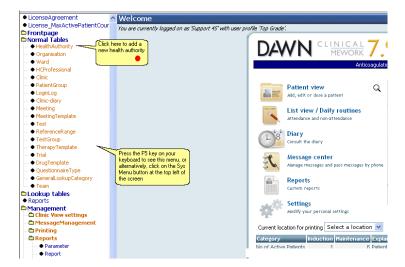


9.16.9 Clinic Diary Slots

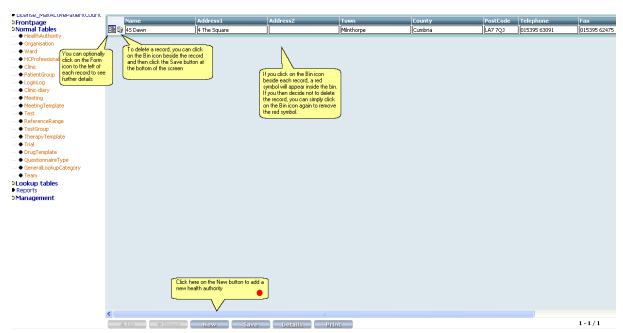


9.17 Adding a Health Authority

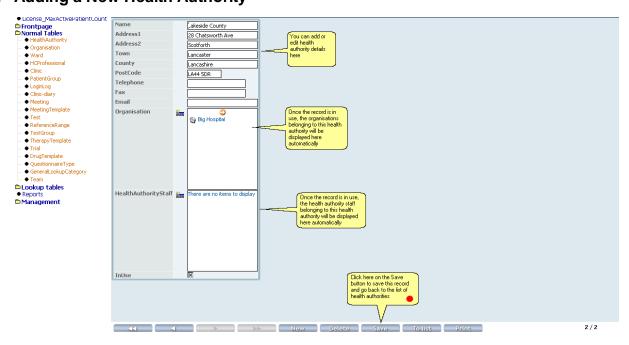
Health Authorities can be added into the system in order to group organisations for reporting purposes. A health authority needs to be added before an organisation can be created.



9.17.1 List of Health Authorities

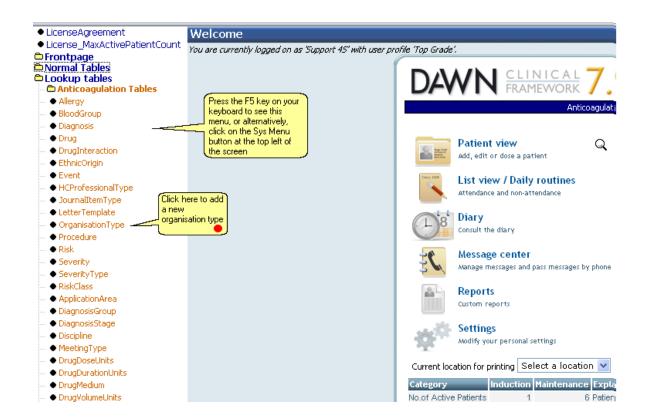


9.17.2 Adding a New Health Authority

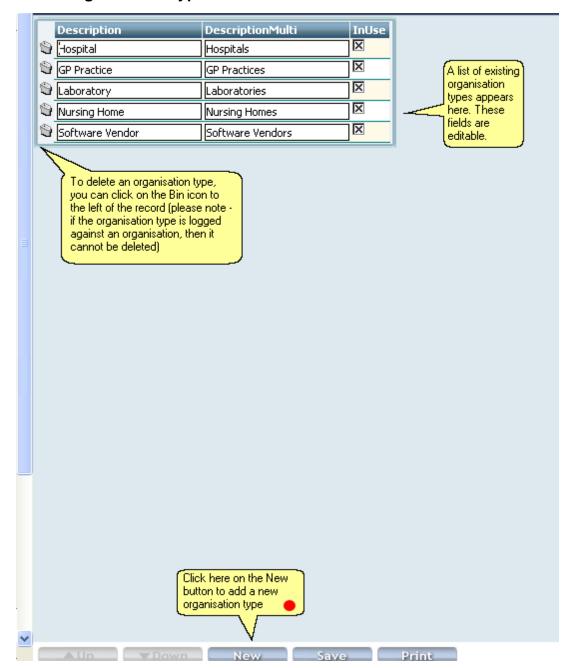


9.18 Adding/Editing Organisation Types

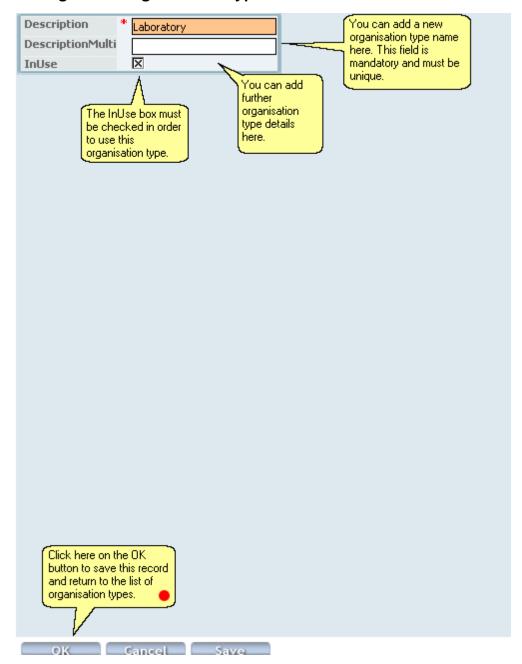
If you need to add a type for an organisation that does not exist in the standard list, new types can be added here.



9.18.1 List of Organisation Types



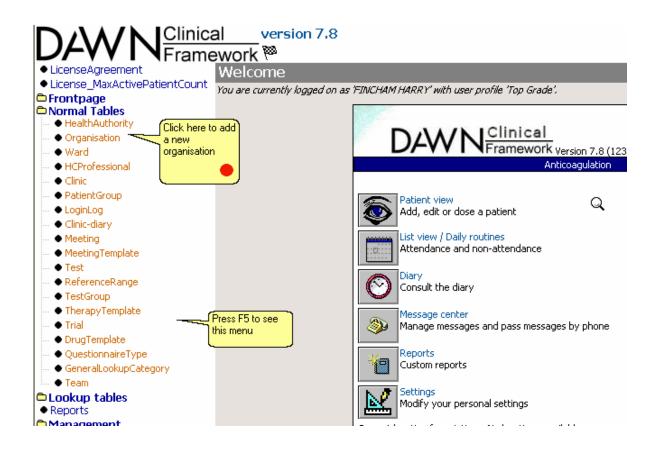
9.18.2 Adding a New Organisation Type



9.19 Adding a New Organisation

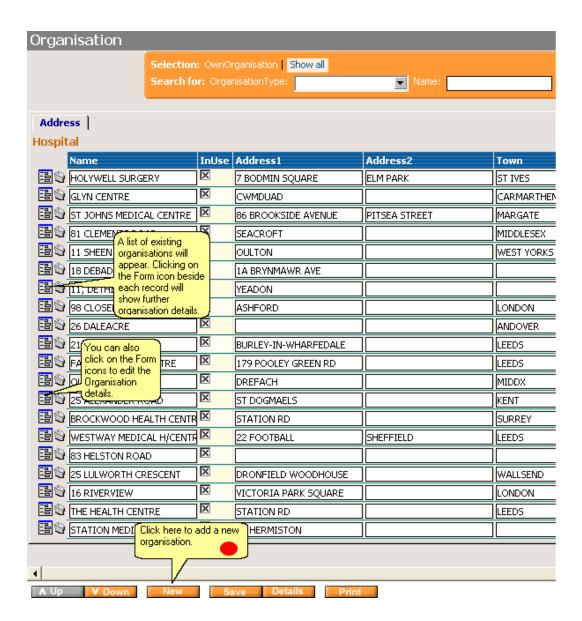
Different organisations can be set up within the system so that healthcare professionals and clinics can belong to a particular organisation. You must have a Health Authority set up within the system before creating a new Organisation.

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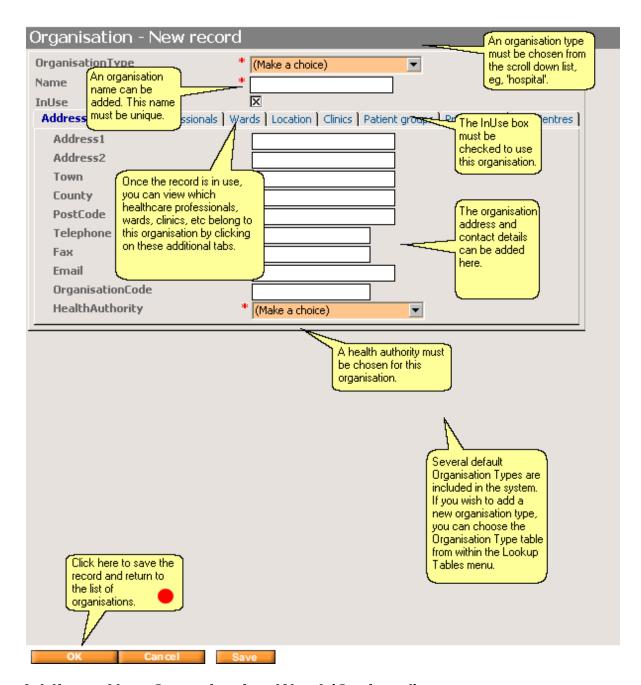


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9.19.1 List of Organisations

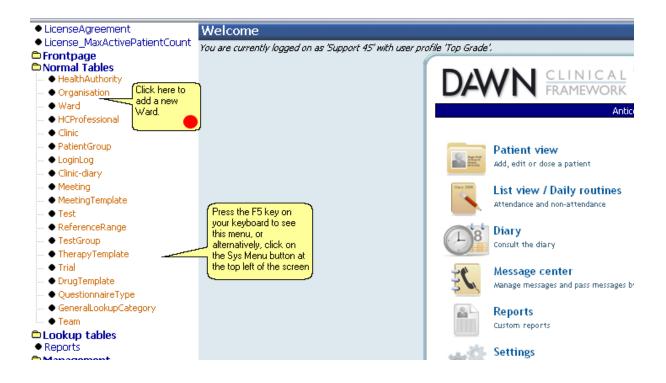


9.19.2 New Organisation Form

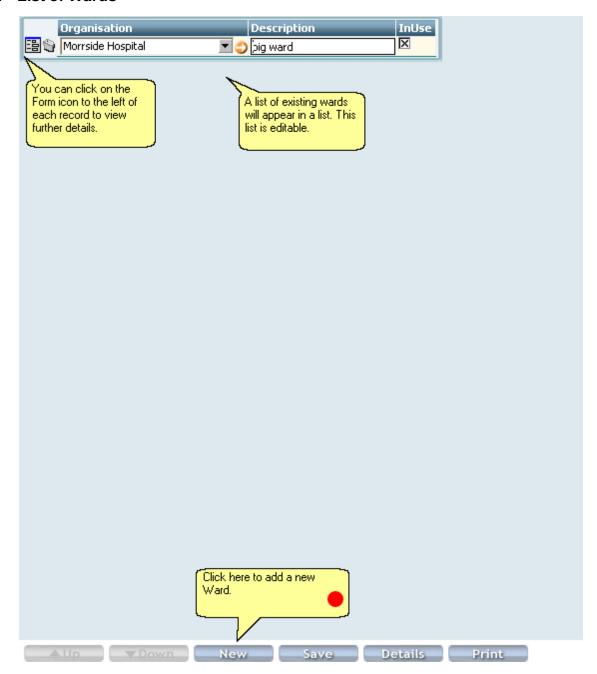


9.20 Adding a New Organisation Ward (Optional)

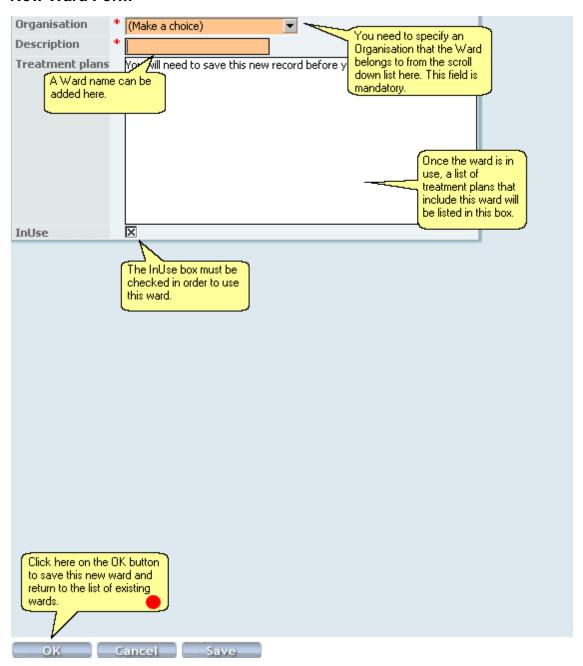
Wards can optionally be set up within the system to monitor inpatients. You must have an Organisation set up within the system before creating a new Ward.



9.20.1 List of Wards

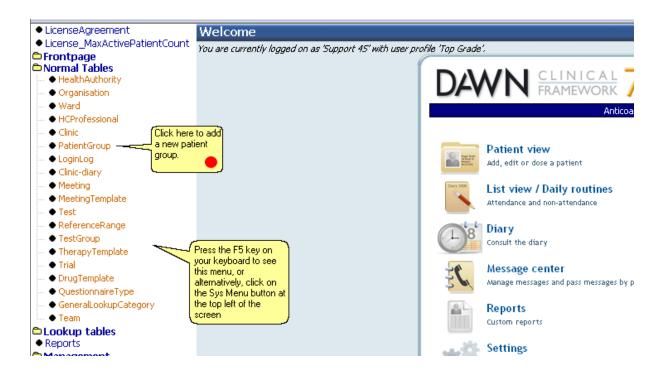


9.20.2 New Ward Form

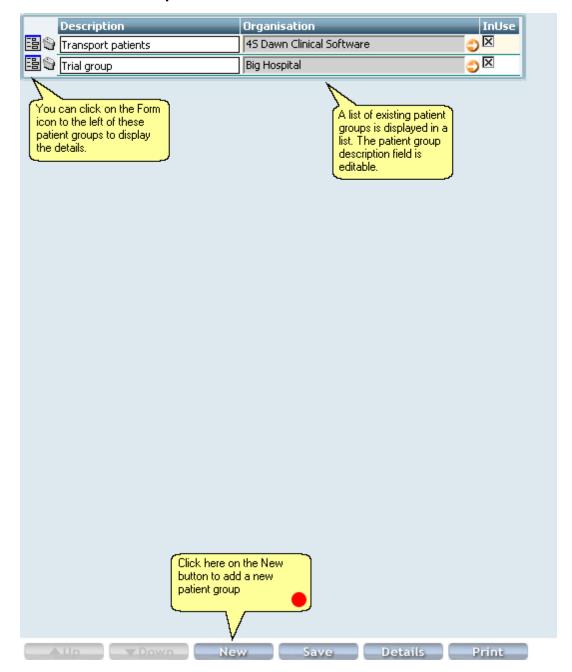


9.21 Adding a New Patient Group (Optional)

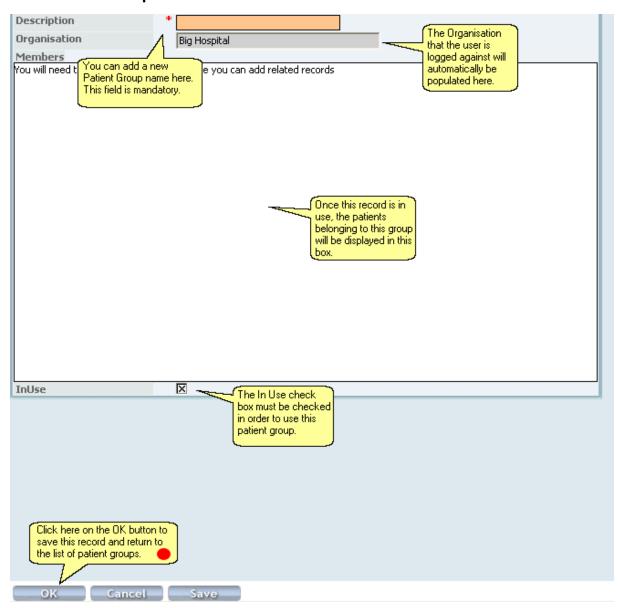
Patient groups are used to group together a subset of patients for use in reporting, list views, research purposes, etc. Patient groups are not a mandatory section to be filled in within DAWN.



9.21.1 List of Patient Groups



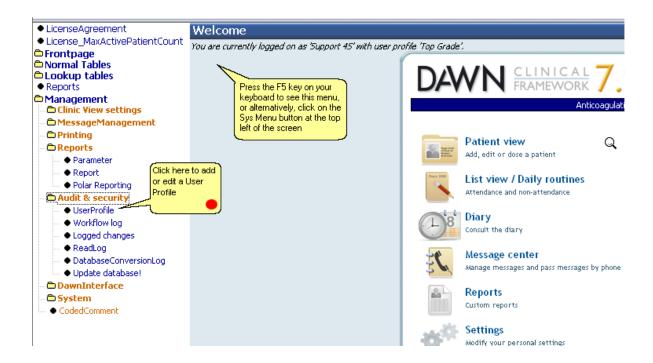
9.21.2 New Patient Group Form



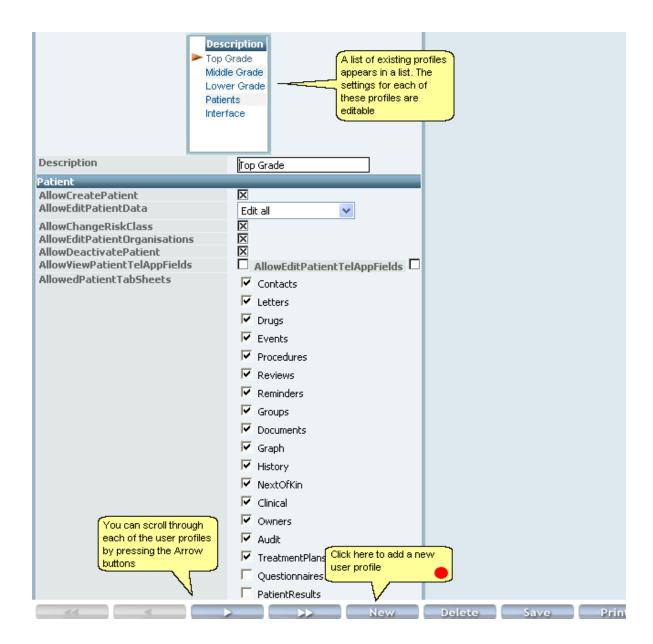
9.22 Adding a New User profile

Several User Profiles can be configured in DAWN and applied to different Healthcare Professionals. Some users require read-only access while others will need to edit certain values in DAWN.

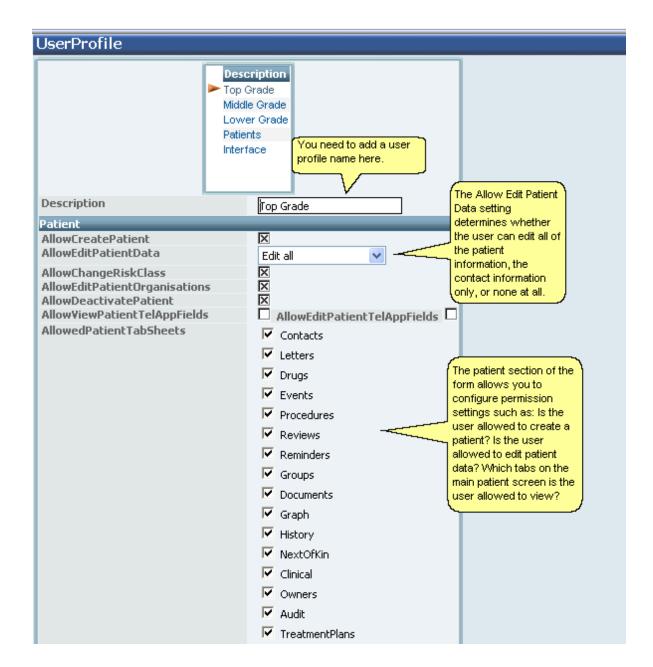
See also the <u>Personal Settings</u> on the Front screen of DAWN - each user can further modify their own access to parts of the DAWN system.

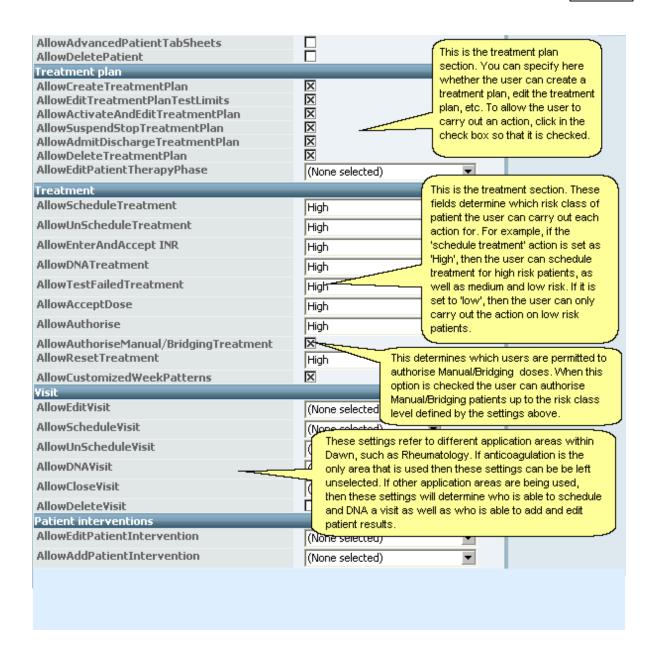


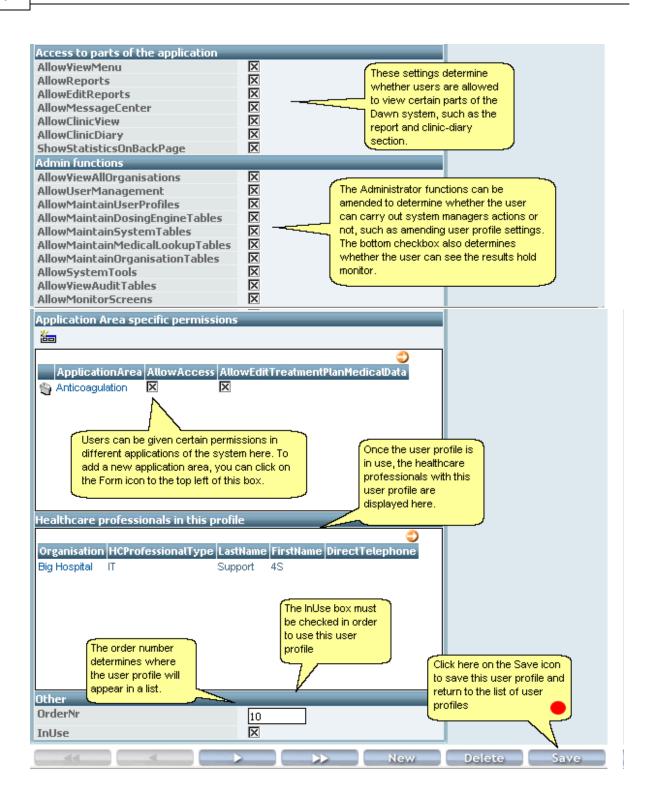
9.22.1 Viewing and Editing Existing User Profiles



9.22.2 Adding a New User Profile

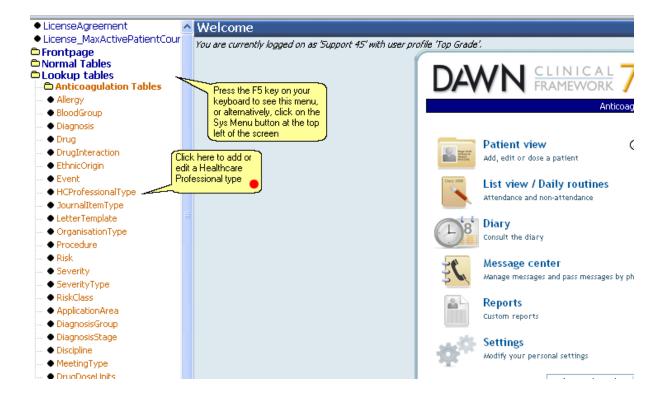




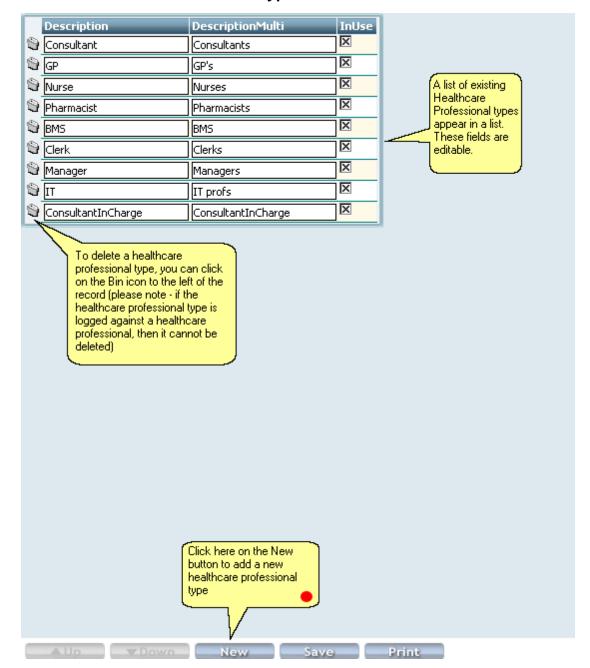


9.23 Adding/Editing Healthcare Professional Types

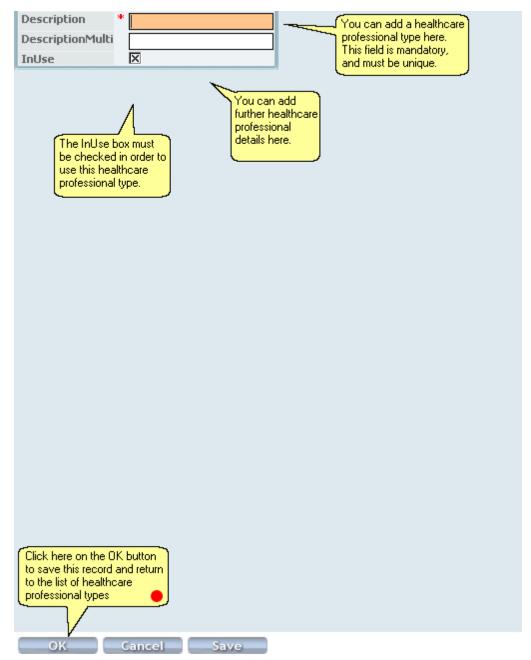
If you need to add a type for a healthcare professional that does not exist in the standard list, new types can be added here.



9.23.1 List of Healthcare Professional Types



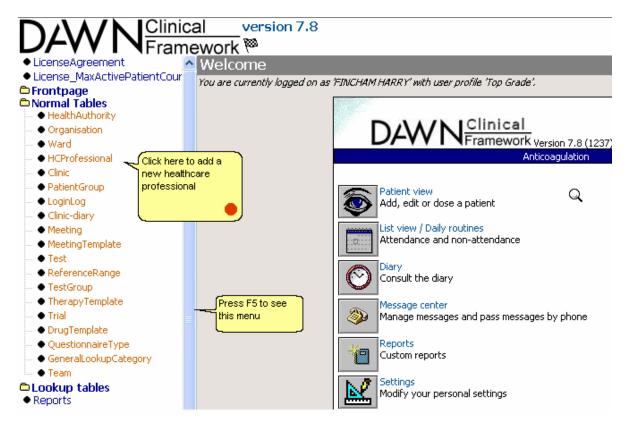
9.23.2 Adding a New Healthcare Professional Type



9.24 Adding a New Healthcare Professional

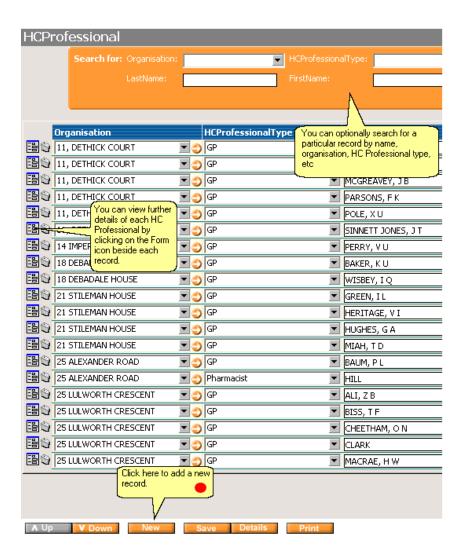
Healthcare Professionals can be added to the DAWN system and can optionally be set up with user accounts to access their patients. Once healthcare professionals have been added to the system they can be logged as a patients referring GP, consultant, etc.

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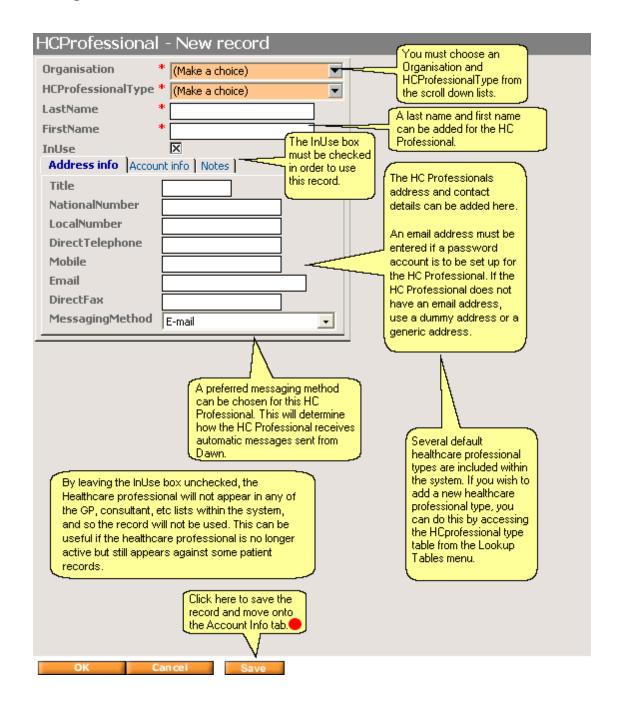


An Organisation must be created before a Healthcare Professional can be added.

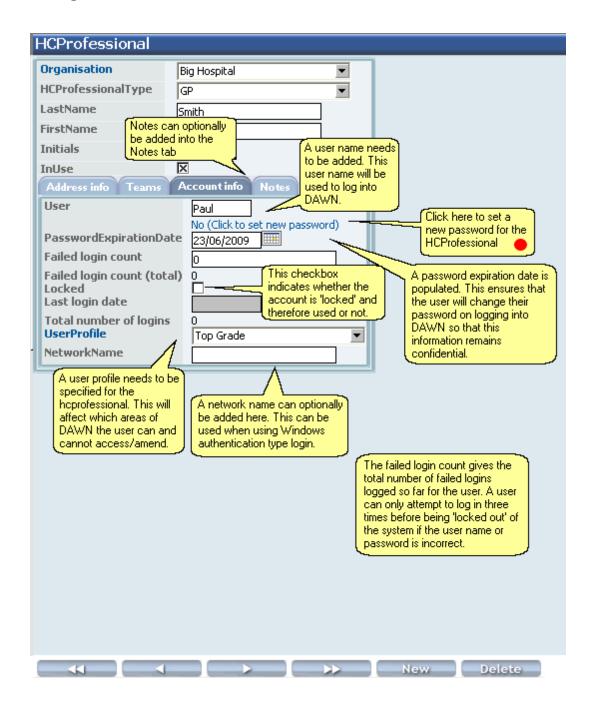
9.24.1 List of Healthcare Professionals



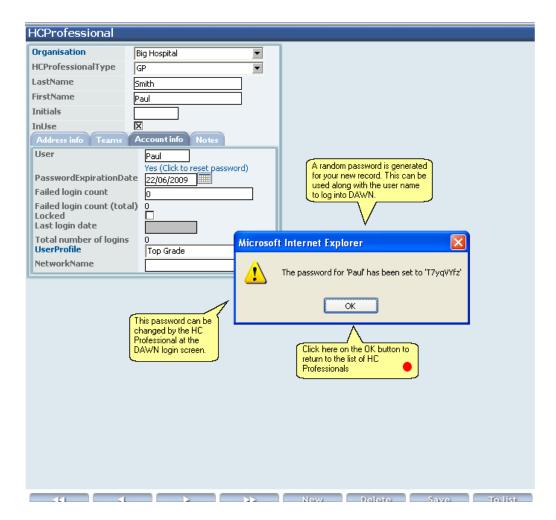
9.24.2 Adding Healthcare Professional Details



9.24.3 Adding Healthcare Professional Account Info



9.24.4 Adding Healthcare Professional Password

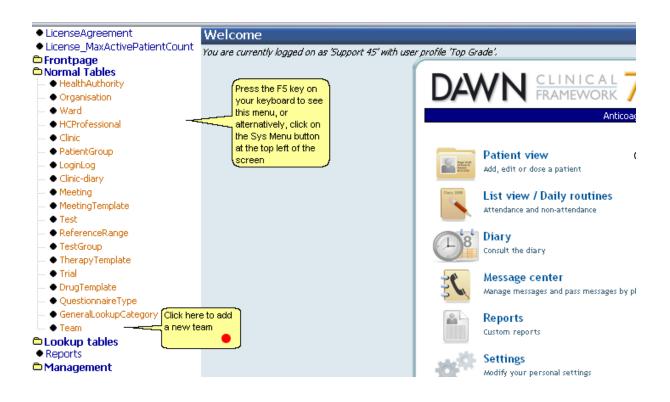


9.25 Adding Teams

You can set up different teams within the system and assign healthcare professionals to them. One or more healthcare professionals can belong to a particular team within DAWN, eg, Rheumatology Consultants, Rheumatology Nurses. Healthcare professionals can also belong to more than one team at a time.

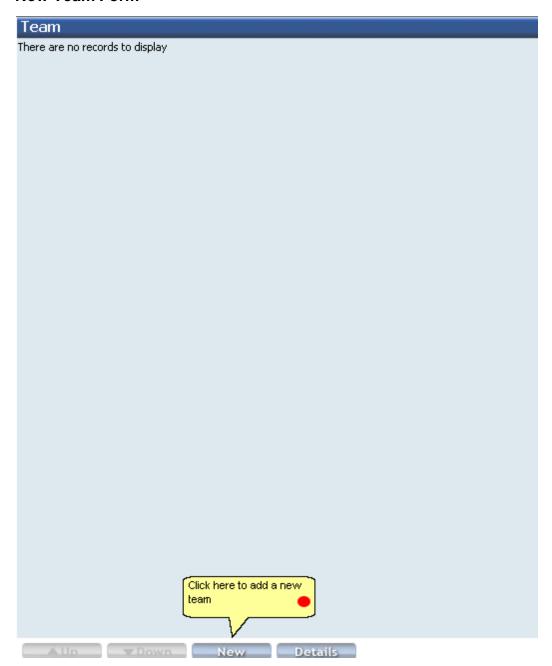
You can filter List Views by team if certain teams are responsible for certain groups of patients. Creating Teams also enables you to use Referrals. A Referral is a request, question or action with regard to a patient's therapy or test results, which you may raise and "refer" to another team for review, advice or as a request for some other action. Click here to learn more about Handling Referrals.

To create a new Team:



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9.25.1 New Team Form



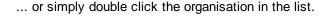
9.25.2 Choosing a New Team Organisation

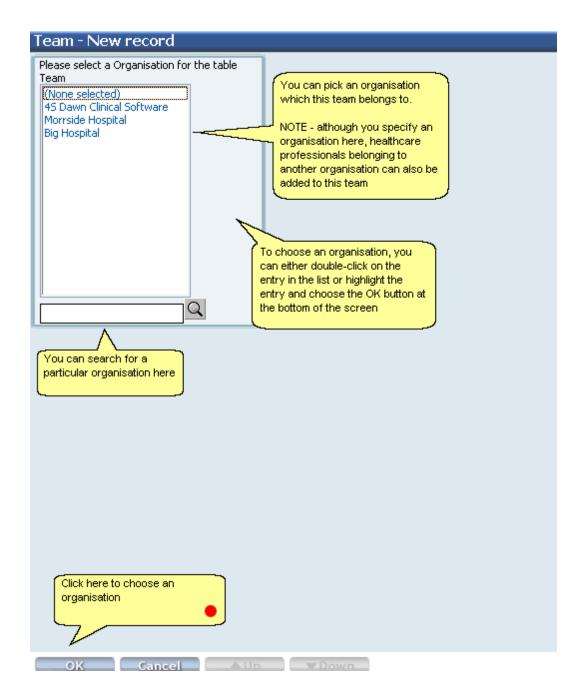
If your service involves several organisations, certain teams might be based at or belong to certain organisations. When you add a new team you can (optionally) select the organisation that the team belongs to.

To select an organisation either:

- 1. Highlight the organisation in the list
- 2. Press the OK button

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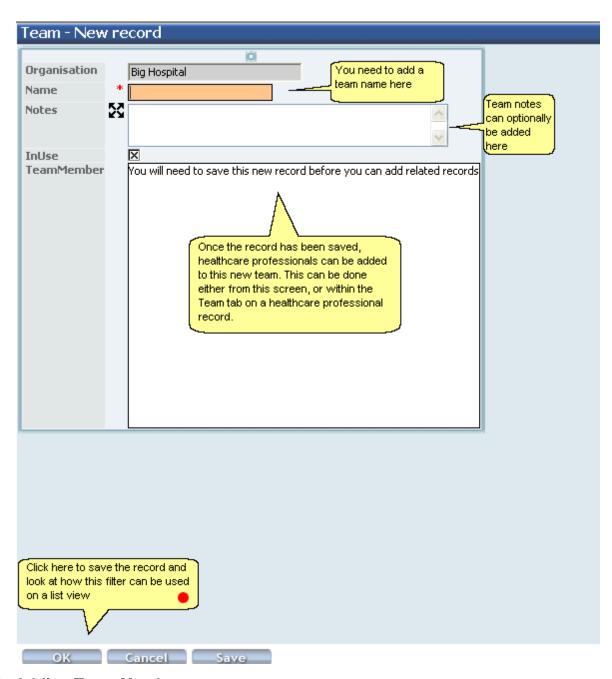


To create a team that does not belong to a specific organisation, click the OK button without selecting an organisation.

9.25.3 Adding a New Team

1. Enter the team name

- 2. Enter any notes about the team (optional)
- 3. Press the save button to create the new team so you can add team members.



9.25.4 Adding Team Members

Once you have created a new Team, you can add members to it at any time using the Team Member list on the Team screen.



It is best to add more than one team member to every team so that patient records can be dealt with when a colleague is absent.

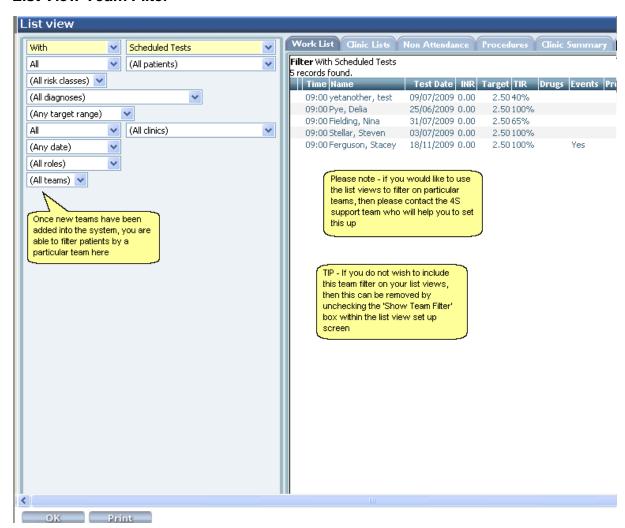
1. Click the new record icon next to the Team Member list.

A healthcare professional selection list appears

2. Select the team member from the list and press the OK button. The new team member appears in the team list.

Click here to learn how to use the List View Team filter to find patients for specific teams.

9.25.5 List View Team Filter



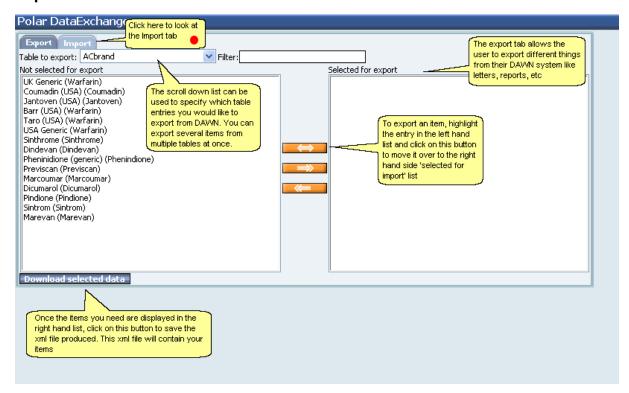
9.26 Data Exchange - to move settings

Data exchange allows users to easily import and export items such as Dosing Regimes, Message Templates, List Views, Custom Modules and Look up tables to and from their DAWN system, without needing to involve the IT department.

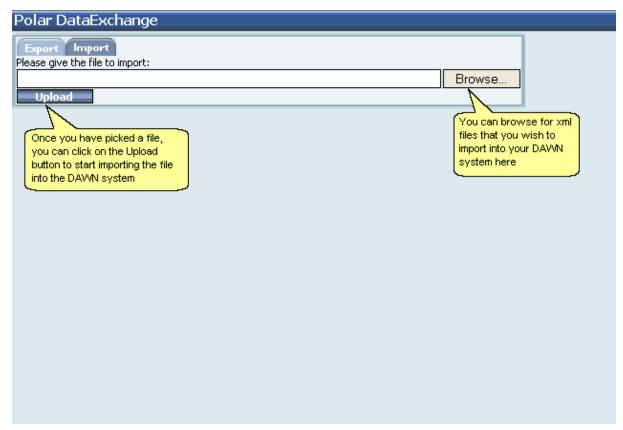
For example, the support team may create a new list view and email it to you as an XML file. You would save the file to your local machine and import it into DAWN using the Data Exchange import facility. The new list view would then be installed and ready for testing.



9.26.1 Export Screen



9.26.2 Import Screen



9.27 Setting up Printing - User Guide

If you wish to print from DAWN manually from a patient record, no setting up is required. DAWN will simply use your internet explorer page settings. You may wish to remove the header/footer and margins as required.

DAWN allows you to automate the generation of messages in response to certain events such as authorising a dose, scheduling a test or rescheduling a non attender. For example, you might configure DAWN AC to print a dosing instruction automatically when you accept a patient's dose.

Depending on certain settings and preferences, each message can be sent to a printer, faxed, emailed or forwarded to the Message Center for telephoning.

To enable automatic and bulk messaging, you must to create a Print Station in DAWN and associate this Print Station with your organization and specific locations within your organisation. When each user logs in, any messages that are triggered in response to things they do (doses they accept, non attenders they reschedule) are handled by their organisation's Print Station.

These messages are printed, faxed or emailed by a separate application called DAWNMailer, which connects to a specific Print Station and sends out all the pending messages to the right location.

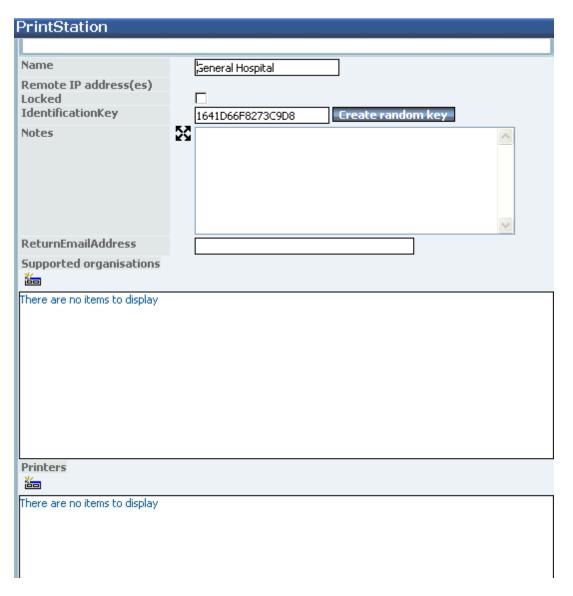
Drivers for all printers at each location should be installed on the server. Should you have identical printers at different locations, the drivers would need renaming to reflect this.

Steps needed to be set up for Automatic Messaging:

- 1. Setting up a Print Station
- 2. Setting Up DAWNMailer to process Messages for a Print Station
- 3. Setting up a new Paper Type
- Mapping Printers with PrinterPaperType
- 5. Setting Up a New Printing Location
- 6. Selecting Paper Type in Message Template
- 7. Selecting Paper Type in Message Event

9.27.1 Setting up a Print Station

- Press F5 to display the system menu and choose Management/Printing/Print Station. (If you are on DAWN version 7.0, choose Normal Tables/Print Station) to display the Print Station screen.
- Choose the orange New button to add a new Print Station.
- Enter a name, eg General Hospital



- Click on Create Random key to generate a unique identification key for this print station and then Save.
- Press the new item button to add the organisations that will use this print station to the Supported Organisations list.
- Leave the Printers list blank. This is automatically populated by DAWNMailer.

The PrintStation handles all Event Messages triggered by users belonging to any of its supported organisations. However, if no DAWN Mailer is running, the messages remain queued inside the print station. You need to set up the DAWNMailer to send out the messages.

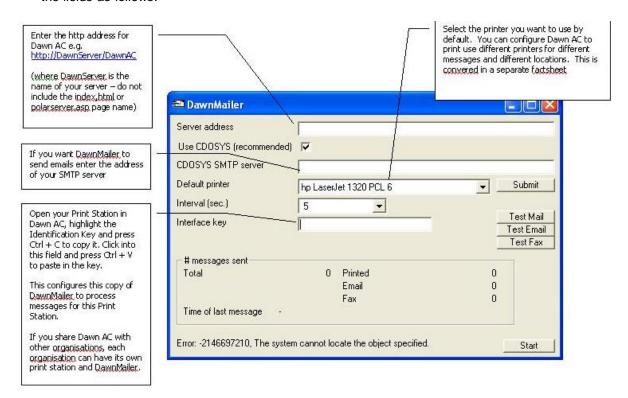
9.27.2 Setting Up DawnMailer to process Messages for a Print Station

DAWNMailer is installed in the Polar Studio/Webroot folder on the DAWN server. It can be run on the server itself or it can be copied to another machine (perhaps a dedicated PC in the anticoagulation department) and run there instead.

If you intend to fax messages, DAWNMailer must reside on a computer that has a modem attached to a phone line. You must also install Microsoft Fax. Microsoft Fax is part of Windows XP and can be set up by choosing the Set Up Faxing option in Windows XP's Printers and Faxes control panel (choose Start/Printers and Faxes).

To set up DAWNMailer

- Create a DAWNMailer folder on the PC where you intend to run DAWNMailer.
- 2. Copy the DAWNMailer.exe and HTMLPrinter.exe (if present) files from the Polar Studio/Webroot folder to your new DAWNMailer folder.
- 3. Double Click DAWNMailer to open the application. DAWNMailer attempts to start automatically. At this point you may receive an error message as DAWNMailer is not correctly configured yet.
- 4. Click OK to close the error message. The DAWNMailer dialog is displayed in Stopped mode. Fill in the fields as follows:

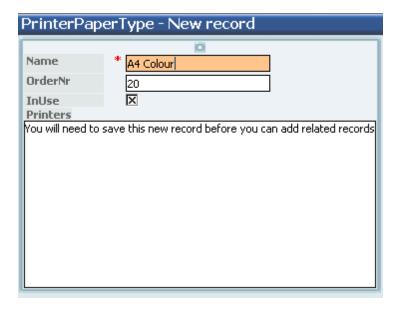


5. Press the Test Mail, Test Email and Test Fax buttons to print, email and fax a test message to ensure DAWNMailer can print, email and fax successfully.

6. Press the Start button to start DAWNMailer. DAWNMailer starts processing any messages for its corresponding Print Station.

9.27.3 Setting up a new Paper Type

- Press F5 to display the system menu and choose Management/Printing/PrinterPaperType.
- Select New.



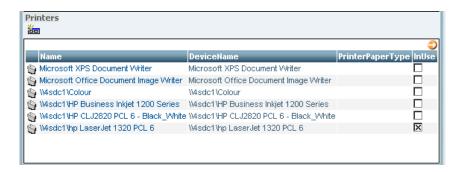
- Enter the Name of the Papertype and order you want it to display in the list.
- · Choose Save.

9.27.4 Mapping Printers with PrinterPaperType

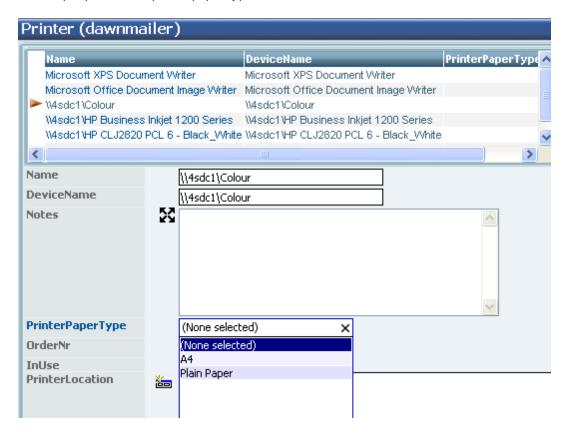
• Press F5 to display the system menu and choose Management/Printing/PrintStation.



- Edit the PrintStation you want to map printers to PrinterPaperType for.
- Scroll down to the Printers section.



• Select a printer from the list of printers in print station interface. This will display the interface used to map a printer with printer paper type.

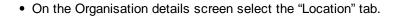


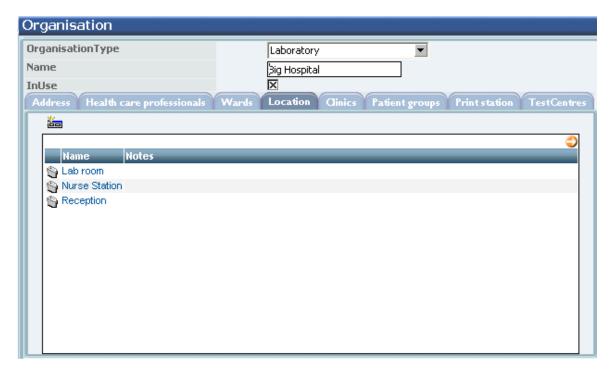
- Select the PaperType from the drop down list.
- · Choose Save.

9.27.5 Setting Up a New Printing Location

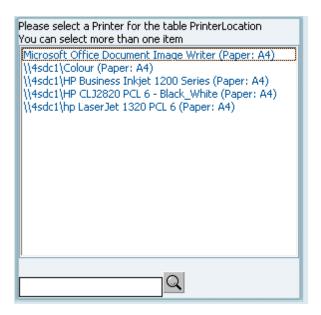
- In DAWN, press the F5 key to display the menu on the left of the screen. Select
- Normal Tables/Organisation. Then select or search for the required Organisation. And click on the "View Details" icon:



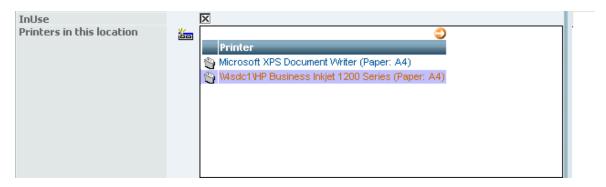




- Click on the "Insert A Record" icon to display the New Record screen.
- Enter a name for the new printing location and click OK. The Organisation "Location" tab will be displayed again.
- Click on the name of the new location to re-display its details.
- Click on the "Insert A Record" icon in next to the "Printers in this location" field to display a list of available printers:



• Select the required printer and click OK (or select multiple printers by holding down the shift key while clicking) to return to the printing location screen.



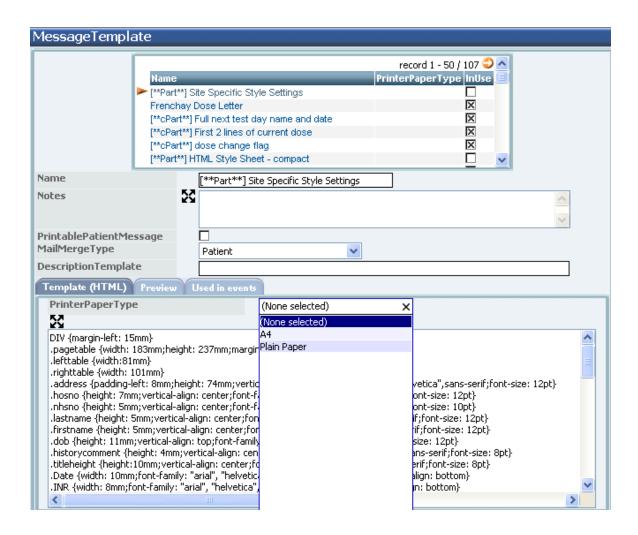
- Select save and the printing location will now be available to all users within the selected Organisation.
- Users can change their printing location from a drop down list on the main DAWN screen.



• The selected printing location is automatically saved, there is no need to reselect the printing location each time the user logs in.

9.27.6 Selecting Paper Type in Message Template

- Press F5 to display the system menu and choose Management/Printing/MessageManagement/ MessageTemplate
- Select the PrinterPaperType for the message. This will ensure that the selected printer will use the correct printer paper type when printing this message template.
- Choose Save.



9.27.7 Selecting Paper Type in Message Event

This will supersede the settings applied for PrinterPaperType in the message template.

- Press F5 to display the system menu and choose Management/Printing/MessageManagement/ MessageEvent
- Edit the message event you are setting the PaperType for.



• Select the PrinterPaperType for the message event. This will ensure that the selected printer will use the correct printer paper type when generating this message event.

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· Choose Save.

9.28 FAQ - settings on DAWN

How do I change the GP for my patient?

Click on Treatment plan and Referral to select a different GP. Interfacing to DAWN may be installed to make this update automatically.



How do I update DAWN when a GP's address changes?

Ask your database administrator to use the System menu, Normal tables, Organisation screen to edit the address of the surgery.

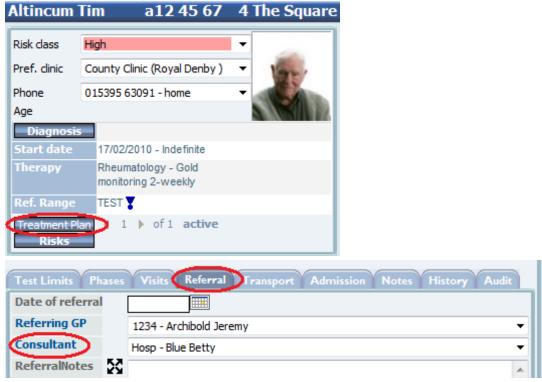


How do I update DAWN when a GP moves to a different surgery?

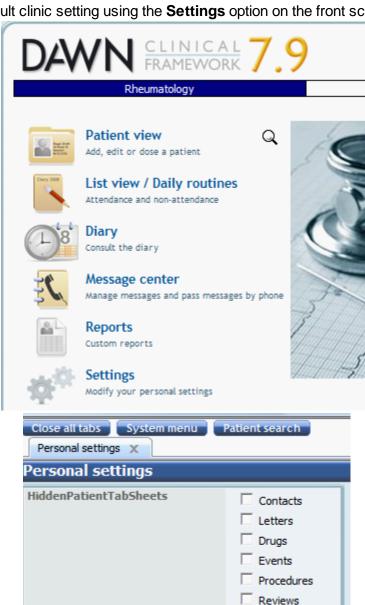
Ask your database administrator to use the System menu, Normal tables, HCProfessional screen to select a different surgery for this GP.

How do I update DAWN when a consultant retires?

Ask your database administrator to use the System menu, Normal tables, HCProfessional screen to mark this consultant as not 'In use'. Transfer each patient to another consultant from their Treatment plan screen



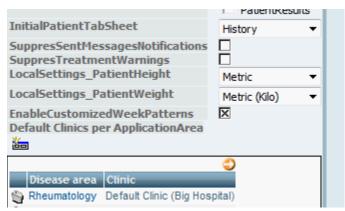
How do I select the same Clinic every time?



Reminders Groups

Choose your default clinic setting using the **Settings** option on the front screen.

Click on the yellow star to add the default clinic



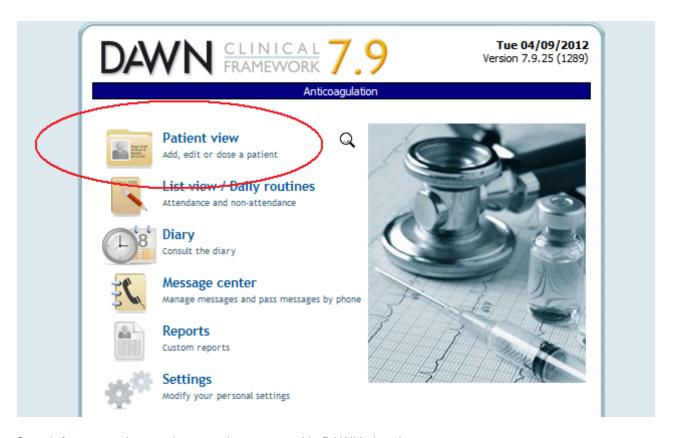
This will save you a step every time you add a treatment plan.

Part

10 Adding a New Patient

There are several steps needed to add a new patient into the system. We go through these in order below.

Ensure you log into the correct area of DAWN by choosing the disease area (like Anticoagulation / Haematology /...) on this front screen <u>before</u> clicking on 'Patient View'.



Search for your patient as they may have a record in DAWN already.

Colonia Asia asia	I para a santa a santa a		I Ch II		
Selection: Active patients	Patients with active 11		app.area Snow all		
Search for: Last name:	Brown	First name:	John	Hosp No:	BG6678229
Town:		County:		Postcode:	
Dateofbirth:		DoD:		Language:	
Home phone:		Mobile phone:		Work phone:	
Next of kin nar	ne:	Next of kin Mob. pho	one:		

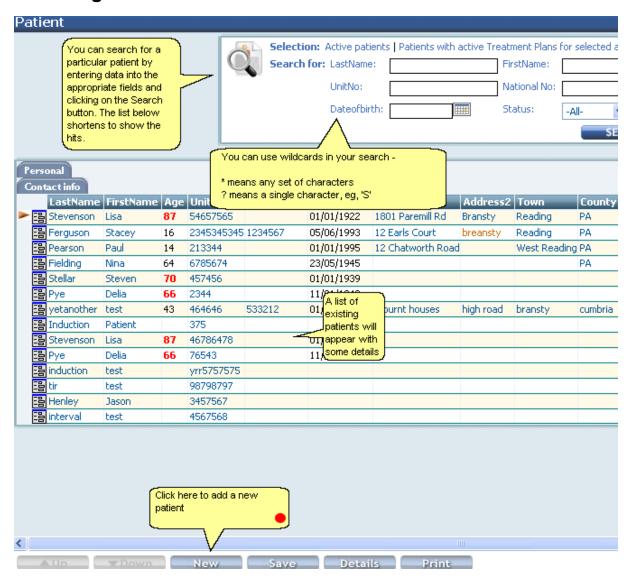
There are no records found that match your criteria

If your patient has no record on DAWN, select 'New' at the bottom of the screen to add a new record.



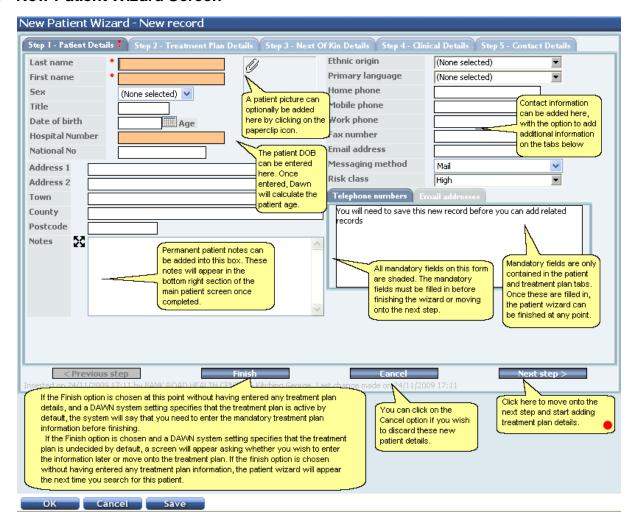
(back to Starting a Non-VKA Treatment Plan page)

10.1 Choosing New Patient Form



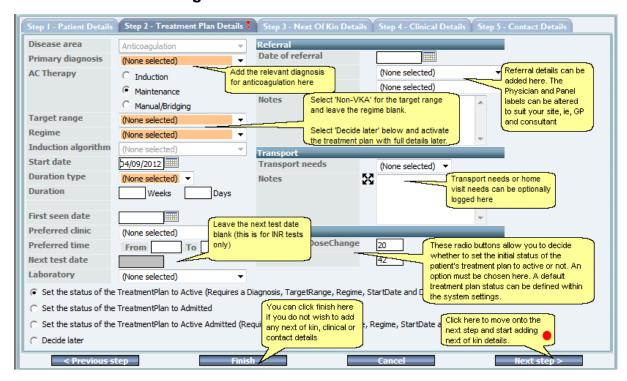
(back to detailed Non-VKA workflow page)

10.1.1 New Patient Wizard Screen



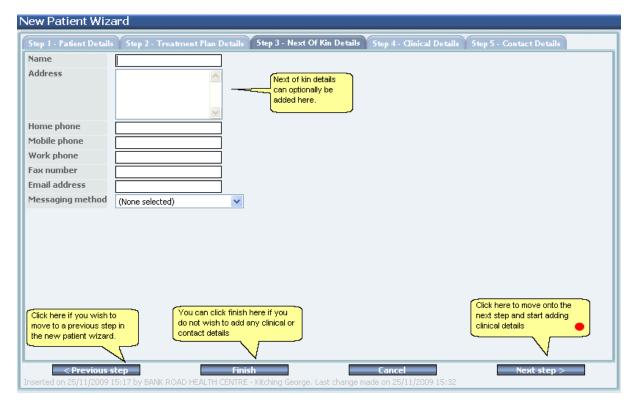
(back to detailed Non-VKA workflow page)

10.1.2 Wizard Screen - Entering Treatment Plan

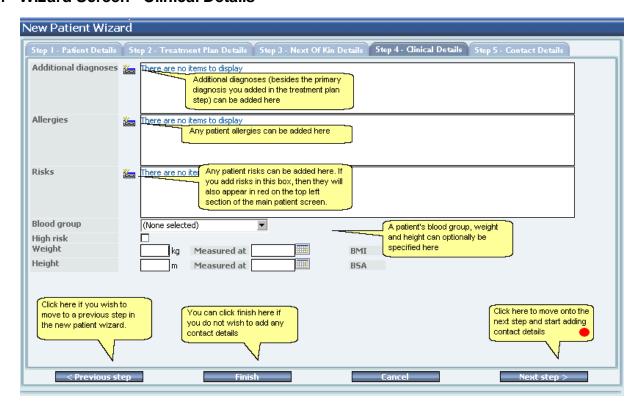


See suggested steps to monitoring non-VKA patients on DAWN for some hints and tips.

10.1.3 Wizard Screen - Next of Kin Details

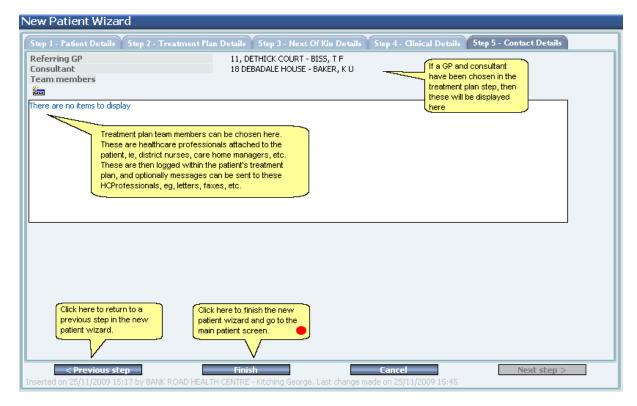


10.1.4 Wizard Screen - Clinical Details

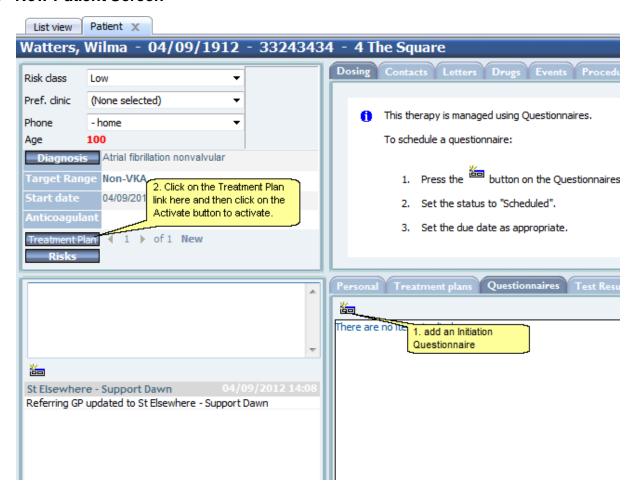


(back to Haemorrhagic Risks page)

10.1.5 Wizard Screen - Contact Details



10.1.6 New Patient Screen

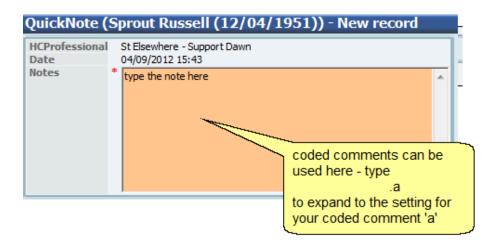


(back to Workflows in DAWN page)

10.2 Adding notes



The Quick Notes are ideal for brief notes about a phone call or recent history of the patient.



10.3 Drug doses

From the main patient screen, choose the Drugs tab and choose from one of the lists of drugs.



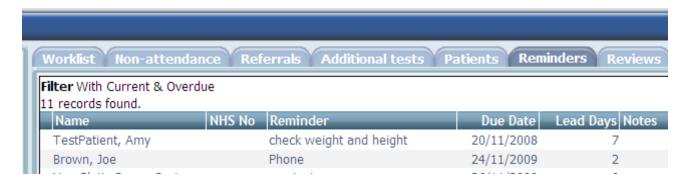


Interactions will be highlighted if used locally.

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10.4 Reminders

The Reminders list view is useful for finding current or overdue Reminders on various patients. The lead days are the number of days before the due date for which you wish to have the Reminder flagged on the Patient screen and the list view.



Add a Reminder from the main patient screen.

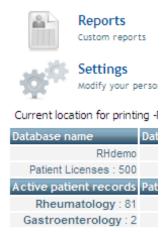


Click on the Reminder and mark it complete.



10.5 Activating and deactivating patient records

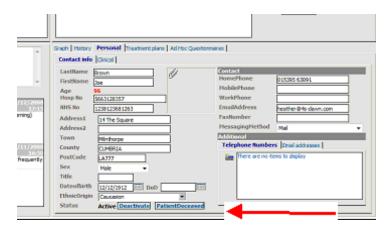
Your active patient license on DAWN is visible on your front screen.



See chapter on Dealing with Clinical Framework Monitoring for guidance on activating treatment plan for an active patient.

Inactivating patient records

- 1. Check that any open referrals and reminders are closed
- 2. Stop any treatment plan for the patient
- 3. On the **Personal** tab, mark the patient as inactive or deceased (this action is reversible in DAWN)



Reactivating patient records

On the **Personal** tab, mark the patient as active (this action is reversible)

Deleting patient records

There is <u>no requirement</u> to delete valid patient records where the patient has moved out of the area or died. Once any treatment plan is stopped, the record can be marked as Inactive or Deceased and will not affect your licensing on DAWN - it can remain on your database for audit purposes.

If you wish to remove a patient record that you have added in error, you must first:

1) Stop any treatment

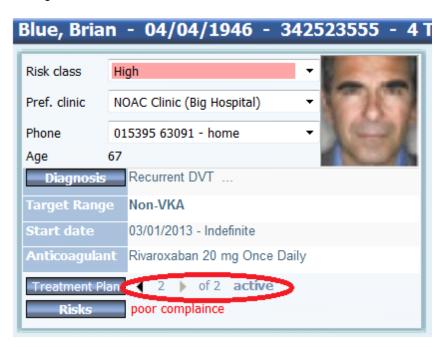
- 2) Delete any/all treatment plan(s)
- 3) Mark the patient as inactive

A Delete button is then displayed so you can delete the patient record.

Part

11 Viewing Patient History

Your patient may have several consecutive treatment plan records and only one of these may be active for their current anticoagulation.



To see previous treatment plans, click on the 'Treatment Plans' tab bottom-right on your patient screen.



If your patient does not have a current active treatment plan record on DAWN, the patient may not appear on the list of scheduled

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patients.

Part

12 Using List Views

DAWN provides *List Views* to assist you with your workflows. *List Views* are lists of patients meeting certain criteria, such as patients waiting on a follow-up.

- You can alter which patients are displayed by selecting different tabs and different filters. In this way
 you can quickly find lists of patients needing, say, appointment reminders or abnormal liver function
 reviews.
- Clicking on a patient in a *List View* opens the patient's record so you can perform any appropriate actions, such as completing a questionnaire or scheduling the next review.
- Closing the patient's record returns you to the list. If the action you have taken means the patient no
 longer meets the criteria (for example they no longer have an unchecked result), they disappear from
 the list. This means you are only left with the patients you still need to deal with.



- 1. Remember there are a number of different lists for different purposes on blue tabs at the top of the screen
- 2. If you select filters on the left to refine the list, remember to remove the filters to check the full list.

Navigating List Views

(back to Workflows in DAWN page)

12.1 Navigating List Views

Click the List view / Daily routines button on the front screen to open the List View screen.

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Wed 01/06/2011 Version 7.9.14 (1281)

Custom reports

Settings

Manage messages and pass messages by phone



Reports

Message center

The *List View* screen consists of a number of tabs. Each tab contains a different *List View* specifically designed to support key activities such as reviewing test results or following up non-attenders.

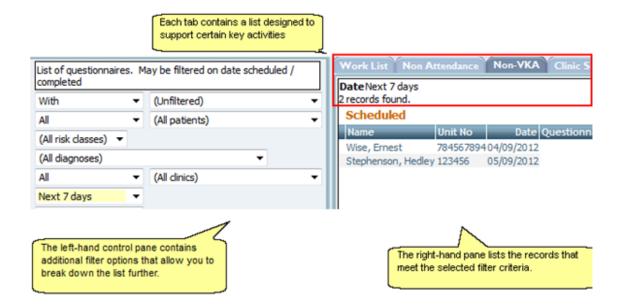
Each individual List View comprises two panes:

- · The control pane
- The list pane

The list pane is the right-hand pane and lists all the patients or tests meeting the selected criteria.

The control pane is the left-hand pane and contains drop down lists of additional filters that allow you to further control which patients or tests are displayed.

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Important notes on using filters – more than one filter may be chosen in the control panel on the left at any time. The following example selects patients in the "Postal clinic" who have "Scheduled or Overdue" appointments for review.



Each filter can then be removed by choosing the default option (like All clinics) again.



Please note:

The **With** or **Without** option applies only to the uppermost filter, i.e. "Scheduled & Overdue" in the example above. In this case, changing the setting to **Without** would select all patients in the Postal clinic who do not have scheduled or overdue review appointments on DAWN. It would not select patients who are not in the "Postal clinic".

• If you use filters to work with subsets of your patients, you must always check the unfiltered list to find patients who do not fit any of the criteria you select.

For example, you may wish to divide up checking flagged results by assigning one clinic to one member of staff and another clinic to a different member of staff. Each person uses the clinic filter to show patients in their clinic and works down their list checking the results. However, a patient who has not yet been assigned to a particular clinic does not appear on either list. As such, someone should always check the list for *all clinics* (which includes everyone) to ensure there is no one left with flagged results that still need checking.

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Part

13 Handling Non-Attendance for Novel Oral Anticoagulant Patients

If a patient fails to attend for a review of their Rivaroxaban therapy, update the scheduled Follow-up questionnaire with a new date for their appointment.



Print any letters / faxes / e-mails as required from the Letters tab.



If a patient persistently fails to attend or have their blood tested you may wish to contact their GP or even discharge them from your monitoring service. You may wish to stop the treatment plan and mark the patient as 'Inactive' on the Personal tab.

13.1 Non-attendance process

explains how to:

- Find patients overdue for review
- Record any necessary action
- Generate a letter (or e-mail) to the non-attending patient

See the following sections for more information:

Using the list view to find patients who are overdue for follow-up

Changing the treatment plan

Printing letters from DAWN using pre-configured templates.

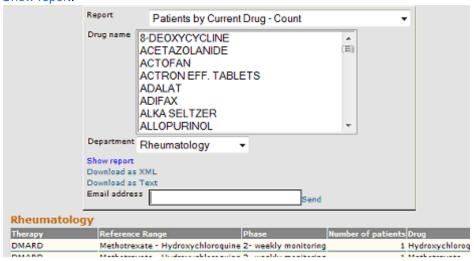
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Part

14 Running Reports



Choose the report from the dropdown menu and select any parameters as required before choosing Show report.



Data may be extracted from DAWN by saving as a text file or e-mailing to yourself or a colleague. Further data analysis may then be possible using Microsoft Excel or another programme.

(back to Workflows in DAWN page)

Part

15 Settings for Novel Oral Anticoagulants

Your System Manager can access settings for Rivaroxaban and other anticoagulants in the **System menu > Lookup tables**.



The settings here are critical to how your DAWN system operates and any changes / deletions / additions are likely to affect the anticoagulant dosing of past / present or future patients. ALL changes to settings should be tested thoroughly on a test database before applying changes in your production database. ALL outputs (like letters / e-mails) from the DAWN system should be checked carefully for completeness and accuracy by a suitably qualified healthcare professional before the patient is instructed.

For a new oral anticoagulant, 4S Information Systems Ltd will supply settings for Anticoagulant, Regime, Non VKA Dose and Questionnaire Settings. It is unlikely that you will need to modify these settings but please contact the support team (support@4s-DAWN.com) with any questions or issues. From time to time, you may need to review of consider updates to the following tables for a particular anticoagulant -

Therapeutic Indications	if Rivaroxaban may be used in a new condition now
Interacting Drugs	if new information emerges on concomitant drugs affecting
	the chosen anticoagulant
Specific Risks	if new conditions are found to affect Rivaroxaban therapy
Regime and Non VKA	to set a completely new dosage and dose settings

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Dose

General Lookup Category to adjust the dropdown menus for CHADS or HASBLED
 Settings scores

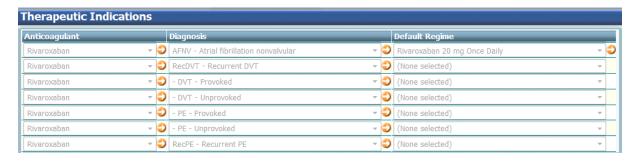
For help and advice on editing any settings in your DAWN system, please contact <u>support@4s-DAWN.com</u>.

15.1 Therapeutic indications

Please Note: The appropriate anticoagulant, diagnosis and regime need to be added to the DAWN system

(if they are not already there) before proceeding to the step below.

The primary diagnosis for your patient has to be set as a valid qualifying diagnosis or 'therapeutic indication' for the particular anticoagulant. For example, the settings for Rivaroxaban may be as shown



Add to these settings as required as new medical evidence emerges so that an anticoagulant is known to be approved for use with a particular primary diagnosis.

NB - deleting entries on this table may result in multiple patients not getting a dose or next appointment.

(back to Settings for New Oral Anticoagulants page)

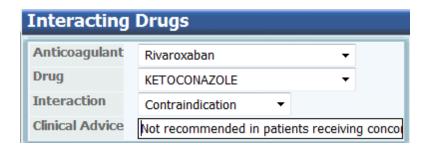
15.2 Interacting drugs for non-VKA

It is possible to link an anticoagulant with a drug which has one of the following interactions if prescribed concomitantly.

- Contraindication
- Haemorrhagic Risk
- Thromboembolic Risk

These settings have a notes field and the notes plus appropriate warnings will display on appropriate patient questionnaires and may prevent activation of a treatment plan. See examples for contraindicated drugs and interacting drugs.

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NB - addition / editing / deletion of entries on this table may cause checks on important drug interactions to be missed.

NB - deletion of an entry for Interacting Drugs may cause loss of information in any patient questionnaire not completed or unlocked for editing.

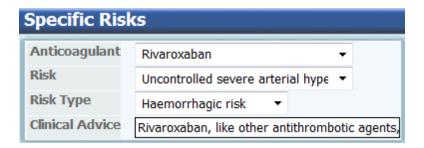
(back to Settings for New Oral Anticoagulants page)

(Technical note - the table name for Interacting drugs is AnticoagulantInteractionDrug)

15.3 Specific Risks for non-VKA

Haemorrhagic risks, thromboembolic risks and contraindicated conditions may be stored in this table for use in patient questionnaires.

These settings populate the questionnaire screens for haemorrhagic risks and other contraindications.



NB - deletion of an entry for Specific Risks may cause loss of information in any patient questionnaire not completed or unlocked for editing.

(back to Settings for New Oral Anticoagulants page)

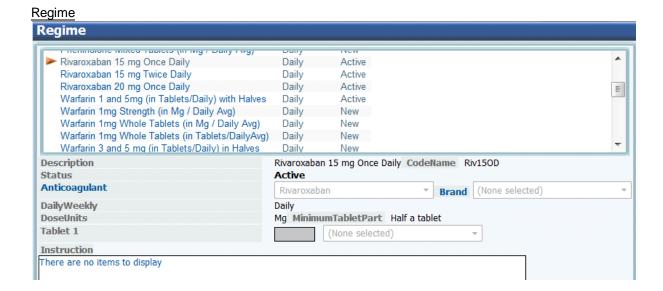
(Technical note - the table name for Specific Risks is AnticoagulantRisk.)

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15.4 Regime and Non VKA Dose

Regime settings are required for each Rivaroxaban (or other non-VKA) dose to be used in DAWN. Each dosage needs to exist as a 'Regime', a 'non-VKA Dose' and as a 'Permitted Regime'.

If a new dosage or dosage frequency is approved you may add this to each of the 3 following tables as appropriate so that the settings are available in a DAWN patient record.

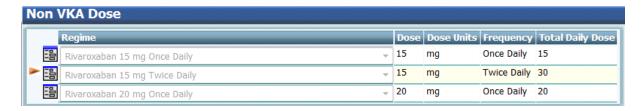


The settings are similar to VKA doses in this table except that no Instructions are required.

NB - deletion of an entry for Regime may result in multiple patients not getting a dose or next appointment.

Non VKA Dose

The settings for non-VKA regimes link to a numeric Total Daily Dose which is stored in this table for reference. Elements of the settings for a chosen regime are compared between the regime chosen in a treatment plan and in the Questionnaires and this is the basis of some of the validation checks on each patient.



Each regime for which a dose check is required needs to have a setting in this table. If a Rivaroxaban **Initiation Questionnaire** requires this dose check, it will not be possible to activate a treatment plan for the new dosage without a setting in this table.

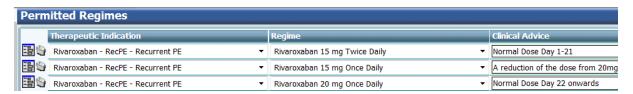


The settings here are critical to how your DAWN system operates and any changes / deletions / additions are likely to affect the anticoagulant dosing of past / present or future patients. ALL changes to settings should be tested thoroughly on a test database

before applying changes in your production database.

Permitted Regimes

Other validation checks are made on first activation of a treatment plan and on saving an Initiation Questionnaire on the settings stating which regimes (*ie* dose of Rivaroxaban for example) are appropriate for which primary diagnosis (or therapeutic indication). Additional regimes can be added to this table as appropriate.



The 'Clinical Advice' is displayed on the <u>Initiation Questionnaire</u> screen as below and the Order number is relevant for display on the questionnaire screen.

Dosing regime	Advice
Rivaroxaban 15 mg Twice Daily	Normal Dose Day 1-21
Rivaroxaban 15 mg Once Daily	A reduction of the dose from 20mg once daily to 15 mg once daily should be considered if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT and PE.
Rivaroxaban 20 mg Once Daily	Normal Dose Day 22 onwards

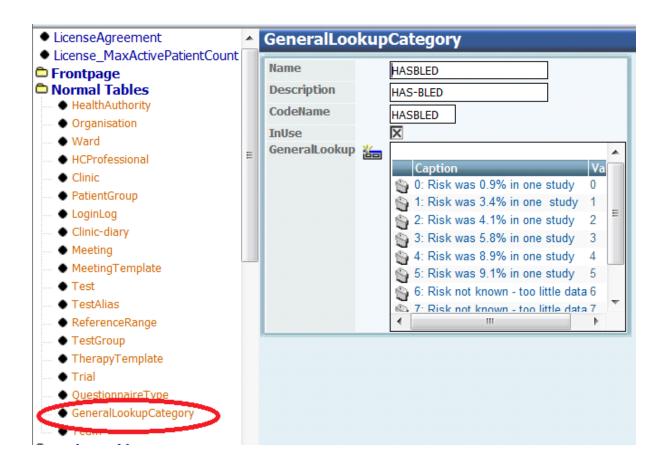
NB - deletion of an entry for Permitted Regimes may result in multiple patients not getting a dose or next appointment.

(back to 'Settings for New Oral Anticoagulants' page)

(Technical note - the table name for Permitted Regimes is AnticoagulantIndicationRegime.)

15.5 General Lookup Category settings for non-VKA

The general lookup category settings are used in some questionnaires. Options available for answering questions on the questionnaire may be edited / added to or deleted from this table.



See CHADS score

NB - renaming or deletion of an entry for General Lookup or General Lookup Category may cause loss of information in any patient questionnaire not completed or unlocked for editing.

(back to Settings for New Oral Anticoagulants page)

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Part

16 Settings for Novel Oral Anticoagulants (4S copy)

Your System Manager can access settings for Dabigatran and other anticoagulants in the **System** menu > Lookup tables.





The settings here are critical to how your DAWN AC system operates and any changes / deletions / additions are likely to affect the anticoagulant dosing of past / present or future patients. ALL changes to settings should be tested thoroughly on a test database before applying changes in your production database. ALL outputs (like letters / e-mails) from the DAWN AC system should be checked carefully for completeness and accuracy by a suitably qualified healthcare professional before the patient is instructed.

For a new oral anticoagulant drug, settings are added to the following tables -

Anticoagulant*

Regime*

Qualifying Risk Factors

Therapeutic Indications*

Interacting Drugs

Specific Risks

Permitted Regimes^{*}

Non VKA Dose

Questionnaire Settings

General Lookup Category Settings

^{*} mandatory settings

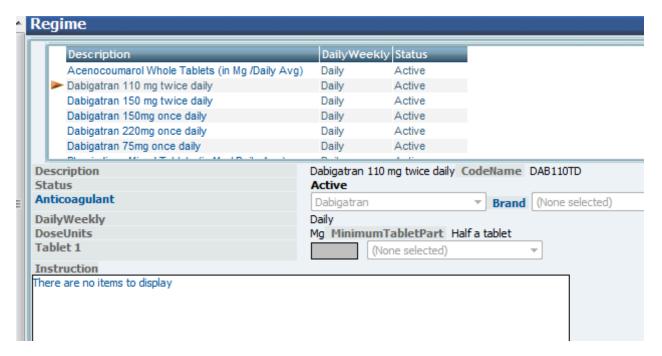
16.1 Anticoagulant for non-VKA (COPY)

An Anticoagulant will be set for each non-VKA but tablet / pill size settings are not required.



16.2 Regime for non-VKA (COPY)

Regime settings are required for each Dabigatran (or other non-VKA) dose to be used in DAWN AC.



The settings are similar to VKA doses in this table except that no Instructions are required.

NB - deletion of an entry for Regime may result in multiple patients not getting a dose or next appointment.

16.3 Qualifying Risk Factors for non-VKA (COPY)

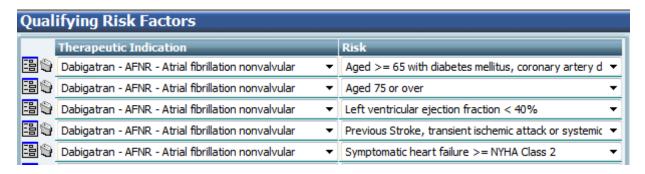
For some anticoagulants, it may be important to note which reason(s) or thrombotic risks have caused the patient to be prescribed this anticoagulant.

If no Qualifying Risk Factors are added, no opportunity to record these risk factors will be provided on an Initiation Questionnaire.

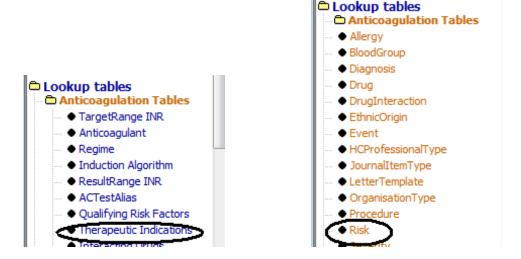
For example, for Dabigatran in AF patients the following risk factors may contribute to the decision to

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prescribe Dabigatran.



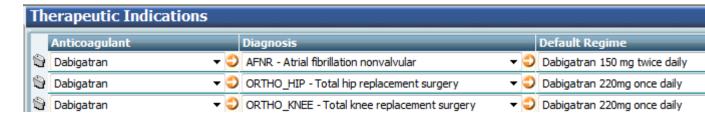
The entries on this table link a **Therapeutic indication** and a **Risk** and you should ensure that the Risk chosen is marked **In Use**.



NB - deletion of an entry for Qualifying Risk Factors may cause loss of information in any patient questionnaire not completed or unlocked for editing.

16.4 Therapeutic indications (COPY)

The primary diagnosis for your patient has to be set as a valid qualifying diagnosis or 'therapeutic indication' for the particular anticoagulant. For example, the settings for Dabigatran may be as shown



Add to these settings as required as new medical evidence emerges.

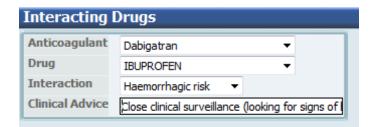
NB - deleting entries on this table may result in multiple patients not getting a dose or next appointment.

16.5 Interacting drugs for non-VKA (COPY)

It is possible to link an anticoagulant with a drug which has one of the following interactions if prescribed concomitantly.

- Contraindication
- Haemorrhagic Risk
- Thromboembolic Risk

These settings have a notes field and the notes plus appropriate warnings will display on appropriate patient questionnaires and may prevent activation of a treatment plan. See examples for contraindicated drugs and interacting drugs.





NB - addition / editing / deletion of entries on this table may cause checks on important drug interactions to be missed.

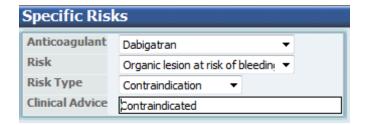
NB - deletion of an entry for Interacting Drugs may cause loss of information in any patient questionnaire not completed or unlocked for editing.

(Technical note - the table name for Interacting drugs is AnticoagulantInteractionDrug)

16.6 Specific Risks for non-VKA (COPY)

Haemorrhagic risks, thromboembolic risks and contraindicated conditions may be stored in this table for use in patient questionnaires.

These settings populate the questionnaire screens for haemorrhagic risks and other contraindications.



NB - deletion of an entry for Specific Risks may cause loss of information in any patient questionnaire not completed or unlocked for editing.

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(Technical note - the table name for Specific Risks is AnticoagulantRisk.)

16.7 Permitted Regimes (COPY)

Checks are made on first activation of a treatment plan and on saving an Initiation Questionnaire on the settings stating which regimes (*ie* dose of Dabigatran for example) are appropriate for which primary diagnosis (or therapeutic indication). Additional regimes can be added to this table as appropriate.



The 'Clinical Advice' is displayed on the <u>Initiation Questionnaire</u> Order number is relevant for display on the questionnaire screen.

screen as below and the

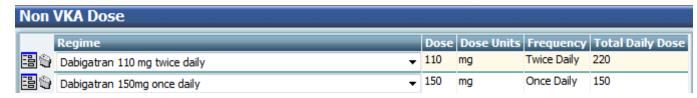


NB - deletion of an entry for Permitted Regimes may result in multiple patients not getting a dose or next appointment.

(Technical note - the table name for Permitted Regimes is AnticoagulantIndicationRegime.)

16.8 Non VKA Dose (COPY)

The settings for non-VKA regimes link to a numeric Total Daily Dose which is stored in this table for reference. Elements of the settings for a chosen regime are compared between the regime chosen in a treatment plan and that chosen in an Initiation Questionnaire.



Each regime for which a dose check is required needs to have a setting in this table. The requirement

for a dose check is set in the 'Questionnaire settings'

table.



The settings here are critical to how your DAWN AC system operates and any changes / deletions / additions are likely to affect the anticoagulant dosing of past / present or future patients. ALL changes to settings should be tested thoroughly on a test database before applying changes in your production database.

16.9 Questionnaire settings for non-VKA (COPY)

Settings in the 'Questionnaire settings' table define which questionnaires are used with particular non-VKA drugs and how they are used.

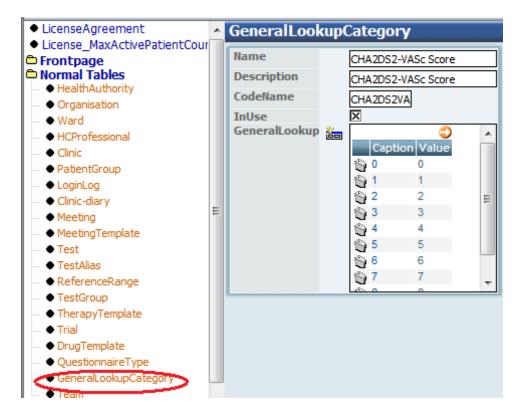
- A questionnaire may be required to be completed before activating a treatment plan.
- The dose selected on the questionnaire may need to be checked against the treatment plan settings on first activation of a treatment plan.
- DAWN AC may prevent a questionnaire from being completed for a patient without an appropriate active treatment plan.



The settings here are critical to how your DAWN AC system operates and any changes / deletions / additions may affect the anticoagulant dosing of patients. ALL changes to settings should be tested thoroughly on a test database before applying changes in your production database. ALL outputs (like letters / e-mails) from the DAWN AC system should be checked carefully for completeness and accuracy by a suitably qualified healthcare professional before the patient is instructed.

16.10 General Lookup Category settings for non-VKA (COPY)

The general lookup category settings are used in some questionnaires. Options available for answering questions on the questionnaire may be edited / added to or deleted from this table.



See CHADS score

NB - renaming or deletion of an entry for General Lookup or General Lookup Category may cause loss of information in any patient questionnaire not completed or unlocked for editing.

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